

स्थानीय एकीकृत विकास समाज नेपाल

Society for Local Integrated Development Nepal (SOLID Nepal)



प. सं.: १

च. नं.: ०२३/०८१/०८२

Date: 24 October 2024

To
Nepal Health Research Council
Ramshahpath, Kathmandu, Nepal

Subject: Site Close-out Report
[Proposal number 282-2022]

Dear Sir/Madam,

Please find attached herewith the site close out report of the clinical trial entitled- A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO-cell) in adults aged 18 years and older, conducted from 25 November 2022 to 31 December 2023 for your kind information.

For your kind information, this clinical trial implemented by SOLID Nepal is sponsored by Jiangsu Recbio Technology Co. Ltd. and CRO for this trial is MSR (Beijing) Pharmaceutical Consulting Co. Ltd.

This site close out report intends to provide the details of the site close out including the follow-up status of the participants. We would like to express our sincere thanks to you for your steady support and smooth close out.

Thank you.

With regards,

Dr. Khem Bahadur Karki

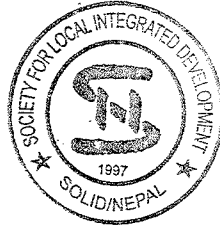
Country PI

Recombinant two-component COVID-19 vaccine (CHO cell)



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**A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to
evaluate the efficacy, safety and immunogenicity of the recombinant two-component
COVID-19 vaccine (CHO cell) in adults aged 18 years and older**



Site Close-Out Report 2024

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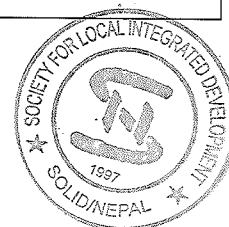
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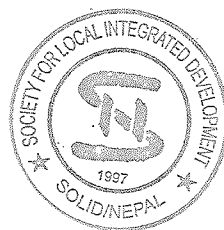
Project Introduction

Title	A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older
Protocol number	REC611C303
Phase	Phase III
Sponsor	Jiangsu Recbio Technology Co., Ltd. A217, Vaccine Engineering Center, 28 Xinglin Road, China Medical City, Taizhou 225316, Jiangsu Province, China
CRO	MSR (Beijing) Pharmaceutical consulting company Ltd , China
Global PI	Dr. Zhaojun Mo, Principal Investigator, Guangxi Center for Disease Prevention and Control, China
NHRC Approval Number	282-2022
Local Implementing Partner	Society for Local integrated Development Nepal (SOLID Nepal) Saatdobato, Lalitpur
Country PI , Nepal	Dr. Khem Bahadur Karki
Country Co-PI, Nepal	Dr. Krishna Gopal Maharjan Dr. Achyut Raj Karki
Site Investigators, Nepal	Dr. Tanka Prasad Barakoti, Provincial Hospital BhadraPur, Jhapa Prof. Dr. Sanjib Kumar Sharma, BP Kiorala Memorial Institute of Health Science, Dharan, Sunsari Dr. Kedar Prasad Centuri, ManaMohan Memorial Medical Collage and Teaching Hospital, Syambhu, Kathmandu.



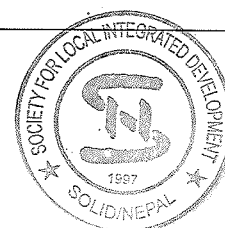
Abbreviation

BPKIHS	BP Koirala Institute of Health Sciences
CRL	Central Reference Lab
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
DDA	Department of Drug Administration
DSMB	Data Safety and Monitoring Board
HURENDEC	Human Rights and Environmental Development Center
ICF	Inform Consent Form
ICH GCP	Good Clinical Practice
IP	Investigational Product
MMMCTH	Manamohan Memorial Medical Collage and Teaching Hospital
MOU	Memorandum of Understanding
NHRC	Nepal Health Research Council
PD	Protocol Deviation
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
SAE	Serious Adverse Event
SM	Social Mobilizers
SOLID Nepal	Society for Local Integrated Development Nepal
UPT	Urine Pregnancy Test
V	Version
WHO	World Health Organization



Major Activities during the Project

22 May 2022	MSR Beijing authorize SOLID Nepal as local representative
30 May 2022	Master agreement between SOLID Nepal and MSR
31 May 2022	Submission of proposal to Ethical Review Board
30 September, 2022	Approval of research proposal from NHRC
10, October 2022	CTA Signed with Provincial Hospital Bhadrapur, Jhapa (Site 1002)
11 October, 2022	CTA Signed with BPKIHS (Site 1001)
12 October 2022	Partner selection Meeting
18 October 2022	Work order signed with MSR
20 October 2022	Approval from DDA
23 October 2022	National Immunization Advisory Committee (NIAC) support letter
23 October, 2022	Agreement with Partner Organization
3 November 2022	First DSMB Meeting
8 November, 2022	Investigational Product (7200 vials) Arrive in Nepal
13 November, 2022	CTA Signed with MMMCTH (Site 1003)
14 November, 2022	Preparation Meeting at Site 1001
15, 16 November, 2022	Site Staff Training at Site 1001
15-24 November, 2022	Site preparation at Site 1001
17 November, 2022	Mock Drill at Site 1001
23-24 November, 2022	Social Mobilizers selection and Training from Udayapur district for Site 1001
25 November, 2022	Vaccine Inoculation piloting at site 1001
25 November, 2022	Observation and monitoring visit by NHRC at site 1001
27 November, 2022	Review Meeting of the piloting at site 1001
28 November 2022	Preparatory Meeting at Provincial Hospital Bhadrapur, Jhapa Site 1002
6-7 December 2022	Social Mobilizers selection and training at Sunsari district for site 1001
7 December 2022	First SAE case at Site 1001
8-9 December 2022	Site Staff training at Site 1002
8-9 December 2022	Social Mobilizers selection and Training at Jhapa Site 1002
10 December, 2022	Mock Drill at Site 1002
12 December, 2022	Piloting of vaccine inoculation at site 1002
13 December 2022	Review Meeting of Piloting at site 1002
16 December 2022	Preparatory Meeting at MMMCTH(Site 1003)
21-22 December 2022	Site staff training at Site 1003



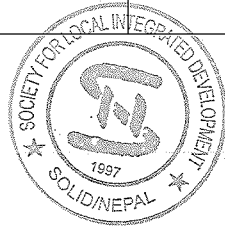
23 December 2022	Mock Drill at site 1003
27 December 2022	Piloting of vaccine inoculation at site 1003
28 December 2022	Review Meeting of Piloting at site 1003
29 December 2022	Documents submission to NHRC for Amendment of Protocol V2.0, ICF v2.1, Diary card V2.0, Participant card v2.0, Monitoring Plan V1.0
2 January 2023	Second DSMB Meeting
11 January 2023	Social mobilizers refresher training at site 1003
13-17 January 2023	DSMB Member observation visit to site 1001 and site 1002
31 January 2023	First community Screening and Health Camp at Sunsari for Site 1001
7 February 2023	NHRC Monitoring visit to site 1003
16 February 2023	Third DSMB Meeting
20 February 2023	Steering Committee meeting
19-24 February 2023	Quality Control Team of CRO visit site 1003
25 February- 3 March 2023	Quality Control Team of CRO visit site 1001
4-10 March	Quality Control Team of CRO visit site 1002
17 March 2023	Last community screening and health camp at Udayapur for site 1001
20 March 2023	NHRC approval on Amended Protocol V2.0, ICF v2.1, Diary card V2.0, Participant card v2.0, Monitoring Plan V1.0
27 March 2023	Forth DSMB Meeting
7-8 April 2023	Orientation on Amended protocol to site staffs and Social Mobilizers at site 1002
10-11 April 2023	Orientation on Amended protocol to Social Mobilizers at site 1001 Udayapur district
12-13 April 2023	Orientation on Amended protocol to Social Mobilizers at site 1001 Sunsari district
20 April 2023	Orientation on Amended protocol to site staffs and Investigators at site 1001
20 April 2023	Orientation on Amended protocol to Social Mobilizers at site 1003
22 April 2023	Orientation on Amended protocol to site staffs and Investigators at site 1002
22 April 2023	Orientation on Amended protocol to Social Mobilizers at site 1002 Jhapa district
24 April 2023	Training on updated protocol v2.0 for CRL
25 April 2023	Swab and serum Sample transfer to CRL



27 April 2023	Orientation on Amended protocol to Social Mobilizers at site 1003 Chitwan district
30 April 2023	Swab and serum Sample transfer to CRL
5 May 2023	Swab and serum Sample transfer to CRL
12 May 2023	Approval from NHRC for export sample shipment to China CRL
12 May 2023	Swab and serum Sample transfer to CRL
14-18 May 2023	NHRC Monitoring visit to site 1001 and 1002
15 May 2023	Fifth DSMB Meeting
21 May 2023	Swab and serum Sample transfer to CRL
28 May 2023	First dose vaccination stop after reaching 4607 participants
29 May 2023	Swab and serum Sample transfer to CRL
1 June 2023	Vaccination venue change of site 1003 from Swayambhu to Dahachowk
1 June 2023	Return of unused IP from site 1003 to central Depot
5 June 2023	Swab and serum Sample transfer to CRL
7 June 2023	MOU with Bakulihar Hospital, Ratnanagar chitwan for Illness management
5-7 June 2023	MSR China Team visit to CRL
8-28 June 2023	MSR China Team visit to site 1001, 1002 and 1003.
11 June 2023	Submission for amendment of Protocol V3.0 to NHRC
13 June 2023	First batch sample shipment from Nepal to China
4 July 2023	Second Steering Committee Meeting
4 July 2023	NHRC Approval for updated protocol V3.0
6 September 2023	Sponsor letter on Termination of efficacy and immunogenicity follow up
8 September 2023	Submission of Sponsor letter on Termination of efficacy and immunogenicity follow up to NHRC
11 September 2023	Sixth DSMB Meeting
19 September 2023	Submission of Continuing Review Application form to NHRC
21 September 2023	Review Meeting at site 1002
22 September 2023	Review Meeting at site 1001
29 September 2023	Review Meeting at site 1003
1 October 2023	Approval for Continuing review request
1-10 October 2023	Monitoring on site documentation
9 October 2023	Blinded Data Review Meeting



10 October 2023	Return unused IP from site 1001
11 October 2023	Return used IP from site 1002
10 November 2023	Destruction of Unused IP
15 November 2023	Participants 9 th Visit follow up complete at all three sites
21 November 2023	Sample shipment from Nepal to China
13 December 2023	Inspection from DDA at site 1003
19 December 2023	Renewal of trial license from DDA
19 December 2023	Review Meeting and farewell of Social mobilizers at site 1002
20 December 2023	Stakeholders Meeting at Sunsari and Udayapur (site 1001)
21 December 2023	Review Meeting and farewell of Social mobilizers at site 1001
31 December 2023	Review Meeting and farewell of Social mobilizers at site 1003
31 December 2023	Site Close Out
23 January 2024	Seventh DSMB Meeting
25 July 2024	Source Documents Storage and Handover to Site 1002
9 August 2024	Source Documents Storage and Handover to Site 1001
18 August 2024	Source Documents Storage and Handover to Site 1003



A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older

1. Background

According to the data released by WHO, as of May 14, 2022, a total of 519,729,804 confirmed cases of COVID-19 and 6,268,281 deaths have been reported in 232 countries or regions around the world. The outbreak and extensive spread of COVID-19 have brought heavy economic pressure and medical burden to people around the world, seriously threatening human survival and health.

In response to this worldwide pandemic situation, the urgent need for safe and effective interventions to mitigate the global spread of SARS-CoV-2 has prompted international efforts to develop antivirals and more efficient vaccines. Up to April 2022, ten vaccines have been validated for WHO emergency use listing since late 2020. Due to the waning of vaccine-induced immunity, as well as the continuous emergence of SARS-CoV-2 variants especially the Omicron strain, breakthrough infection cases continuously increase. The WHO also warned that the Omicron variant can be markedly resistant to neutralization by serum from individuals that were fully vaccinated with one of the four widely used COVID-19 vaccines. All this evidence highlighted the global needs of new strategies for COVID-19 vaccine, to combat the impact of emerging SARS-CoV-2 variants among widespread populations.

2. Objective

Primary

- To evaluate the efficacy of ReCOV in preventing Reverse Transcription-Polymerase Chain Reaction (RT-PCR) confirmed symptomatic COVID-19 in adults aged 18 years and older.

Secondary

- To evaluate the safety and reactogenicity of ReCOV in adults aged 18 years and older.
- To evaluate the efficacy of ReCOV in preventing RT-PCR confirmed symptomatic COVID-19 with various severity in adults aged 18 years and older.
- To evaluate the immunogenicity of ReCOV in adults aged 18 years and older. (immunogenicity subgroup only)
- To compare the immunogenicity of ReCOV between Asian and Non-Asian in the immunogenicity subgroup.
- Genotyping of SARS-CoV-2 virus nucleic acid sequence of COVID-19 cases to evaluate the possible viral mutations.



3. Study Design

This study is a multicenter, randomized, double-blinded, placebo-controlled Phase III clinical trial. The objectives are to evaluate the efficacy, safety, and immunogenicity of ReCOV in adults aged 18 years and older who have not received any COVID-19 vaccination, and have no history of known COVID-19 in previous 6 months. Three-dose intramuscular vaccination schedule (21 days interval) will be applied. About 10000 participants (about 15% participants $\geq$ 60 years old) with SARS-CoV-2 antibody (IgM and IgG) negative at baseline, will be randomized in a ratio of 1:1 to receive ReCOV (20 μ g) or placebo on Day 0, Day 21, and Day 42, respectively. Participants will be stratified by age (18-59 years, $\geq$ 60 years) and study sites (if applicable). The primary endpoint is RT-PCR confirmed symptomatic COVID-19 cases (regardless of severity) that occurred $>$ 14 days after 3 doses vaccination.

4. Agreement and Approval

SOLID Nepal in collaboration with MSR Beijing (Clinical Research Organization -CRO) and partner organizations had proposed to conduct clinical research on “**A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older**”. The Master Agreement between SOLID Nepal and the MSR Beijing had signed on 30 May 2022. After that agreement, SOLID Nepal had processed for NHRC/ERB and DDA approval as per the standard of Nepal Government.

SOLID Nepal had submitted the research proposal on 31 May 2022 for the clinical trial and got the final approval from NHRC on 30 September 2022. After NHRC Approval SOLID Nepal got the approval from DDA on 19 October 2022.

A tri-patriate signature on Clinical Trial Agreement (CTA) had signed by the Country PI of Nepal, Site Investigators of selected three sites and the representative of CRO. The CTA with provincial Hospital Bhadrapur, Jhapa (Site 1002) was carried out on 10 October 2022 and with BPKIHS (Site 1001) was carried out on 11 October, 2022. Similarly, with MMMCTH (Site 1003) was carried out on 13 November, 2022. After these CTA signed, site preparation and documentation process were gear up for enrolment of vaccine participants in each three sites.

5. Vaccine Participant Enrollment and Follow up Visit

SOLID Nepal adopted a field-based clinical trial model for the third phase of the clinical trial on the recombinant two-component COVID-19 vaccine (CHO cell). Initially, site 1001 (BPKIHS) was



prepared for vaccine inoculation, and the first participant was enrolled on 25 November 2022. A total of 2,097 participants were enrolled at site 1001 between 25 November 2022 and 28 May 2023. Of these, 2,015 participants successfully completed the third dose of vaccination for the study.

Site 1002 (Provincial Hospital, Bhadrapur) enrolled its first participant on 12 December 2022, and a total of 1,504 participants were enrolled there between 12 December 2022 and 28 May 2023. Similarly, site 1003 (MMMCTH) enrolled its first participant on 27 December 2022, with a total of 1,006 participants enrolled at site 1003 between 27 December 2022 and 28 May 2023. In total, 4,607 participants were enrolled across the three sites. Of these, 507 participants were part of the safety immunogenicity cohort, and the remaining 4,100 were part of the safety efficacy cohort. There was an 8% dropout rate for completing the third dose.

In the end, a total of 4,064 participants (88%) successfully completed the ninth visit schedule according to the clinical trial protocol version 3.0. All follow-up visits were completed by 15 November 2023 at all three sites. The details of participant enrollment and their follow-up visit records are attached in Annex I.

6. Community Screening and Consenting

As a vaccine trial is also known as Filed trial, the trial was designed for community mobilization and participation to reach out the healthy participants for enrollment. For this reason, SOLID Nepal arranged 33 different screening camps to identify the eligible candidate and carrying out the consenting from 31 January 2023 to 17 March 2023 in Udayapur and Sunsari Districts. A total of 1,125 participants were enrolled for vaccination at site 1001 through community camps. It was observed that these community-level screening camps created a conducive environment for the study at the community level. The dates and venues of these 33 camps are attached in Annex II.

7. End-points Cases

One of the objectives of this third-phase clinical trial in Nepal was to evaluate the efficacy of ReCOV in preventing RT-PCR confirmed symptomatic COVID-19 of various severities in adults aged 18 years and older. During the trial period, suspected cases of COVID-19 infection, commonly known as end-point cases, were closely monitored through community mobilizers. A total of 187 end-point cases [87 cases from site 1001, 77 cases from site 1002, and 23 cases from site 1003] were confirmed by the Central Reference Lab.



8. Sever Adverse Effects and Pregnancy Cases

During the clinical trial, participants were observed for any adverse reactions and illnesses from the first dose of vaccine inoculation to 180 days after the third dose. Social Mobilizers and Investigators were responsible for regularly monitoring them and managing any illnesses or adverse reactions. Total of 28 cases of serious adverse events (SAEs) across all three sites were reported, including 8 participant deaths. All cases were thoroughly presented to the local DSMB board, which determined whether these cases were related to the study vaccine. The local DSMB concluded that none of the 28 SAE cases were associated with the study vaccine. A detailed list of SAE cases is attached in Annex III a.

The eligibility criteria for participation in the vaccine trial included a requirement that women of reproductive age were not pregnant. During the eligibility screening phase, a urine pregnancy test (UPT) was conducted, and after inoculation, participants were advised not to become pregnant for 3 months following vaccination. Male participants were also counseled to avoid impregnating their female partners for 3 months from the inoculation of the vaccine. However, some female participants were reported as pregnant after receiving the vaccination. A total of 26 pregnancies were reported during the study period—20 involving female participants and 6 involving male participants' partners. As of this reporting date, 6 pregnancy cases turned into full term delivery, 1 case turned into post mature delivery, 11 cases turned into induced/elective abortion, and 3 cases turned into false pregnancy. Despite multiple attempts, remaining 5 cases were not in contact with social mobilizers and site investigators. The details of the pregnancy cases are attached in Annex III b.

9. Termination of efficacy and immunogenicity follow up

The sponsor sent a letter for termination of efficacy and immunogenicity follow-up from September 4, 2023 and the letter received on September 6, 2023. The decision was based on the continuous mutation of SARS-CoV-2 Virus, accumulated evidences of immune escape of Omicron and its sub lineages, and recent recommendations from the WHO to drop the ancestral strain and switch to a monovalent vaccine that contains an XBB.1 descendant lineage. Following the receivable of the letter from the Sponsor regarding the termination of efficacy and immunogenicity follow-up, the letter informing the Sponsors decision was submitted to NHRC on September 8, 2023.

An online meeting was convened to discuss on the sponsor's resolution to discontinue the efficacy and immunogenicity follow-ups, provide updates on the status of all three research sites, respond to inquiries from partner organizations, and engage in a comprehensive discussion about the project's future direction. This meeting facilitated productive discussions and led to a consensus. It played a crucial role



in ensuring that partner organizations were well-informed and that their concerns regarding the research project's future were adequately addressed. The letter from Sponsor is attached herewith in Annex VI

10. Preliminary Data Analysis Meeting

During the study period, a preliminary blinded data review meeting was held online on 9 October 2023. The purpose of this meeting was to check and assess the data as of 18 July 2023 before breaking the blind and finalizing the primary analysis. The meeting agenda included a study overview, data management overview, COVID-19 cases and PD summary, SAE overview, statistical analysis overview, and a question-and-answer session were discussed in that meeting.

Participants in the Data Review Meeting included the global PI, Dr. Zhaujun Mo, Country PI for Nepal, Dr. Khem Bahadur Karki, Country PI for Russia, Dr. Dania Saenko, Executive Director of Recbio (the Sponsor) Mr. Ryan Wen, and 9 others from the Sponsor, as well as the General Manager of MSR Beijing (the CRO) Mr. Gaokui Zhang and 9 others from the CRO.

11. Remaining Vaccine Dispose

The clinical trial successfully reached its project closeout phase. A total of 14,400 vaccine vials were imported into Nepal. Out of this, 1,194 vials remained after the completion of vaccine inoculation at all three sites in Nepal.

SOLID Nepal developed vaccine disposal guidelines on the basis of WHO guidelines and the Government of Nepal's Health Care Waste Management Guideline 2014, which were approved by the Country PI of this clinical trial. The remaining 1,194 vaccine vials and 2,831 empty vials were disposed at Site 1003 (Manamohan Hospital, Dahachowk, Kathmandu) in coordination with the DDA. A safety pit for COVID-19-related waste management was made available on the premises of Manamohan Hospital, Dahachowk, and SOLID Nepal used this safety pit for vaccine disposal. The vaccine disposal report, which was submitted to the DDA, is attached here in Annex IV.

12. NHRC Monitoring Visits

On November 25, 2022, Research Officer from NHRC Ms. Richa Acharya, Research Officer, Ms. Santoshi Adhikari, Mr. Shashi Verma and Admin staff Mr. Subash Ghising visited the site 1001, BPKIHS Dharan, Sunsari. They observed the piloting of the vaccine trial and provided their feedback and suggestions for further improvement of the clinical trial.



Similarly, on December 12, 2022, the vaccine inoculation at site 1002 was started at site 1002, Provincial Hospital Bhadrapur, Jhapa. NHRC Monitoring Team was there for the observation of vaccine inoculation. On February 7, 2023, NHRC conducted a monitoring visit at site 1003. The monitoring team consisted of various members, including ERB Chairperson Prof. Dr. Ramesh Kant Adhikari, ERB members Prof. Dr. Jeevan B Sherchand, Dr. Diptesh Aryal, and Mr. Narayan Prasad Khanal. In addition, Ms. Namita Ghimire from the Ethical Review M&E Section, Research Officer Ms. Richa Acharya, and Mr. Shashi Verma from NHRC were also present during the visit. The monitoring team carefully observed the overall setup of the site, participant flow, vaccination process, and documentation of the vaccine trial. They actively engaged in assessing the procedures and practices followed at the site. After the visit, the team provided valuable feedback and suggestions for further improving the clinical trial. Their input aimed to enhance the overall quality, compliance, and ethical standards of the trial.

The NHRC Ethical Review Board (ERB) members conducted a monitoring visit at site 1001 and 1002 from 14-18 May, 2023. The monitoring team included Prof. Dr. Rajeev Shrestha, Dr. Diptesh Aryal, IRC representative from BPKIHS, Ms. Namita Ghimire from the Ethical Review M&E Section, Research Officer Ms. Santoshi Adhikari, and Admin Assistant Mr. Subash Ghising from NHRC. During the visit, the monitoring team carefully assessed various aspects of the trial, such as the site's overall setup, participant flow, Informed Consent Process, vaccination procedures, and documentation. Their aim was to ensure compliance with ethical standards and proper implementation of the trial protocols. After their observations, the monitoring team provided valuable feedback and suggestions for enhancing the overall quality and ethical standards of the trial. The recommendations are expected to contribute to the improvement and smooth conduct of the clinical trial.

13. Inspection from DDA at site 1003

On December 13, 2023, the Department of Drug Administration (DDA) conducted an inspection at the clinical trial site 1003. There were four representatives from DDA and a pre-meeting was conducted with site investigators as a part of inspection. During the inspection, the DDA representatives meticulously reviewed both documents and the procedural aspects of the clinical trial. The thorough examination included a request for specific documents, all of which were promptly submitted for review. These documents encompassed crucial aspects of the trial, such as bioanalytical sample shipment records, blood sample collection processes, calibration reports, IP records, Lab assessment reports and SOPs related to various aspects of the trial, including risk management and vaccine administration.



14. Social Mobilizer Farewell and Certification

On December 19, 2023, a comprehensive review meeting and farewell event was organized at Birtamode, Jhapa for the Social Mobilizers and the staff from the local partner who actively participated in the clinical trial from site 1002. On December 21, 2023, a comprehensive project review and farewell event was organized in Sunsari District for the Social Mobilizers engaged in the clinical trial from site 1001. Similarly, On December 31, 2023, a farewell event for the Social Mobilizers from site 1003 was conducted. During the event, Country Pi expressed heartfelt gratitude towards the Social Mobilizers and the local partner, acknowledging and appreciating their dedicated efforts and significant contributions to the success of the clinical trial. The Social Mobilizers took the opportunity to share valuable insights into their experiences working in the field, highlighting both achievements and challenges faced throughout the trial. Additionally, the Social Mobilizers shared personal growth and development, emphasizing how their involvement in the clinical trial has enhanced their skills in areas such as community engagement, interpersonal communication skills, and effective issues management. The event served not only as a farewell but also as a platform to recognize the essential role played by the Social Mobilizers in achieving the objectives of the clinical trial. To express further appreciation, each of the Social Mobilizers as well as the staff from the local partners were provided with an appreciation certificate during the event, acknowledging their dedicated service and valuable contributions to the clinical trial.

15. Site Activities Close Out

On December 31, 2023, the formal closure of all three clinical trial sites within the project in Nepal was executed, marking a crucial phase in trial management. Following the closure, investigators received directives to ensure the confidentiality and integrity of essential trial elements, including source documents, trial master files, and participant-related information, in accordance with the ICH GCP standards. In alignment with these standards, investigators were underscored the ongoing duty to maintain the confidentiality of trial-related materials, emphasizing the secure handling of pertinent documents and information. Despite the official closure of the sites, investigators are tasked with continued responsibilities, such as accommodating sponsor audits, facilitating monitoring visits from regulatory authorities, and addressing any future work associated with the clinical trial.

16. Source Document Storage and Handover to Site Investigators

Source document storage is one of the major tasks of site closeout. According to ICH-GCP standards, the protocol version 3.0 and signed CTA, source documents will be stored under the protection of site



investigators of three sites for 5 years after the last participant's last scheduled visit. SOLID Nepal arranged for the handover of source documents to the site investigators. All source documents were listed and verified by SOLID Nepal and the sites. These verified source documents were placed in boxes/trunks, labeled with a list of contents, locked, and properly sealed. A handover receipt was signed by both SOLID Nepal and the site representatives.

At site 1001, the handover receipt was signed on 9 August 2024; at site 1002, it was signed on 25 July 2024; and at site 1003, it was signed on 18 August 2024.

The stored source documents include randomization number slips, participant identity forms and cards (copies of citizenship), V1-V9 worksheets, signed ICFs, participant diaries (both solicited and unsolicited), RT-PCR test reports, UPT test reports, rapid antibody test reports, participant file binders, kit dispensing logs, IP disposition, collection and preparation forms, IP dispensing logs, AE logs, sample requisition forms (immunogenicity only), completion/end-of-study forms, and other study-related files, folders, and registers. The signed handover receipts are attached here in Annex V.

17. Remaining Task under the Project

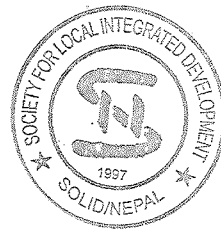
This study was designed as multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older. Among the vaccine participants, there was 1:1 ratio of vaccine and placebo arm groups. After completion of all study process and preliminary data analysis, the un-blinding list should be shared with Country PI Team and Sites. After completion of all field base activities (nearly 9 months), the un-blinding list of participants is not received yet. SOLID Nepal as an implementing partner of CRO (MSR Beijing), is waiting the un-blinding list of vaccine participants from CRO and Sponsor.

It is an ethical responsibility of CRO and Sponsor that, those participants who received placebo vaccine, should be received real vaccine either the same product or the government approved any other vaccine product for COVID-19 protection. Till date, the country PI and his team do not receive any further plan of revaccination for placebo arm group of participants from CRO. We are hopeful that the CRO and the sponsor will provide the details of the participants who require vaccines and its appropriate intervention. Furthermore, Data processing is ongoing and hopeful to receive the overall results of the trial very shortly.

It's also noteworthy to mention that the CRO-MSR Beijing is now out of contact. However, MSR Nepal is here and working on behalf of MSR Beijing. SOLID Nepal as implementing partner is trying its level



best to get the remaining payments of the work from the CRO and the sponsor, but they are not responding properly. However, we are hopeful to clear and close out the financial part of the trial project too..



Annexes

Annexes files are separately attached herewith.



Annex I

Annex I
Vaccine participant enrollment and their visit record

	V1 (Screening)	V2 (Dose 1)	V3 (Dose 2)	V4 (Dose 3)	V5	V6	V7	V8	V9
1001	3027	2097	2015	1979	507	289	1950	1913	1903
1002	1987	1504	1417	1363	N/A	N/A	1323	1343	1338
1003	1417	1006	935	892	N/A	N/A	823	786	823

V1: Screening (0 Days)
V2: First Dose (0 Days)
V3: Second Dose (21 Days)
V4: Third Dose (42 Days)
V5: V4 + 7 Days (New Added Visit)
V6: V4 + 14 Days (For Immunogenicity Group only)
V7: V4 + 28 Days
V8: V4 + 90 Days (New Added Visit)
V9: V4 + 180 Days

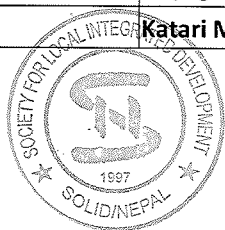


Annex II

Annex II

List of Community Consenting and Health Camps with date and venues

SN	DATE	VENUE
1	Tuesday, January 31, 2023	Barahachhetra - 8, Dobhan, Sunsari
2	Wednesday, February 1, 2023	Barahakshetra- 8, Dovan, Sunsari
3	Thursday, February 2, 2023	Barahakshetra- 3, Bange, Sunsari
4	Friday, February 3, 2023	Barahakshetra- 3, Bange, Sunsari
5	Sunday, February 5, 2023	Belaka Municipality, Satpatre, Udayapur
6	Monday, February 6, 2023	Belaka Municipality, Bhalmandi, Udayapur
7	Tuesday, February 7, 2023	Chaudandigadhi Municipality, Beltar, Udayapur
8	Wednesday, February 8, 2023	TNP, Madan Bhandari Aakha Aspatal ,Udayapur
9	Thursday, February 9, 2023	TNP, Madan Bhandari Aakha Aspatal,Udayapur
10	Friday, February 10, 2023	Katari Municipality, Sombare,Udayapur
11	Sunday, February 26, 2023	Chaudandigadhi Municipality, Madibas, ,Udayapur
12	Tuesday, February 14, 2023	Barahakshetra-2, Sagarmatha Tole, Sunsari
13	Thursday, February 16, 2023	Barahakshetra-11, Madhuban, Sunsari
14	Friday, February 17, 2023	Koshi- 3, Laukahi , Sunsari
15	Saturday, February 18, 2023	Koshi- Bhandabari, Sunsari
16	Sunday, February 19, 2023	Inuruwa-3, Sunsari
17	Monday, February 20, 2023	Duhabi -9, Sunsari
18	Tuesday, February 21, 2023	Barju Rural Municipality, Sunsari
19	Friday, February 24, 2023	Barahakshetra-11, Madhuban, Sunsari
20	Monday, February 27, 2023	Chaudandigadhi Municipality, Barkhe Danda, ,Udayapur
21	Tuesday, February 28, 2023	Belaka Municipality, Shikharmadi, ,Udayapur
22	Wednesday, March 1, 2023	Chaudandigadhi Municipality, Hadiya, Udayapur
23	Thursday, March 2, 2023	TNP, Madan Bhandari Aakha Aspatal ,Udayapur
24	Friday, March 3, 2023	TNP, Madan Bhandari Aakha Aspatal ,Udayapur
25	Saturday, March 4, 2023	TNP, Madan Bhandari Aakha Aspatal ,Udayapur
26	Sunday, March 5, 2023	Railway line, Dharan, Sunsari
27	Wednesday, March 8, 2023	Gadhi RM – 2, Sunsari
28	Sunday, March 12, 2023	Harinagar – 1, Sunsari
29	Monday, March 13, 2023	Duhabi – 10, Sunsari
30	Tuesday, March 14, 2023	Bhokhara Narsing Municipality , Sunsari
31	Wednesday, March 15, 2023	Itahari – 1, Sunsari
32	Thursday, March 16, 2023	Triyuga Municipality, Madan Bhandari Aakha Aspatal , Udayapur
33	Friday, March 17, 2023	Katari Municipality, Lamiduwali Adharbhat Vidyalyaya, Udayapur



Annex III

1. The first part of the Annex III is the list of the countries which are not members of the European Union but which are members of the European Free Trade Association (EFTA). The list is as follows:

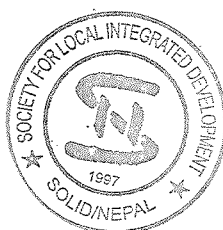
2. The second part of the Annex III is the list of the countries which are not members of the European Union but which are members of the European Free Trade Association (EFTA). The list is as follows:

Annex III a
List of SAE cases during trial period

List of Total SAE cases			
Case No.	Site	Subject ID	Event Term
1	1001	100100090	Alcohol Withdrawal
2	1003	100300087	Chicken Pox
3	1002	100200580	Hypertensive Emergency
4	1003	100300668	Fever
5	1002	100200101	Death
6	1002	100200698	Upper Respiratory Tract Infection
7	1003	100300262	Abdominal Pain
8	1001	100100123	Seizure episodes
9	1001	100100209	[Death] Right sided body weakness with slurring of speech
10	1001	100101024	Death
11	1003	100300661	Diabetes mellitus
12	1002	100200105	Tuberculosis
13	1003	100301405	Alcohol withdrawal syndrome (generalized tonic-clonic seizures)
14	1003	100301134	Pneumonia
15	1001	100100940	Death (Electrocution)
16	1001	100102010	Undifferentiated acute febrile illness
17	1001	100102782	Suicide
18	1003	100300477	Community acquired pneumonia and alcohol dependent system
19	1003	100300966	Lower Respiratory Tract Infection and Anemia
20	1001	100101969	Episode of Seizure
21	1003	100300882	Seizure disorder with alcohol dependent syndrome
22	1003	100300950	Diabetes mellitus (uncontrolled) with chest infection
23	1003	100300656	Urinary Tract Infection
24	1003	100301383	Death
25	1002	100200629	Pancytopenia under evaluation
26	1001	100101046	Death [Unknown]
27	1002	100201420	Alcoholic with jaundice with drug induced liver injury hepatitis with renal injury
28	1001	100101796	Spontaneous abortion

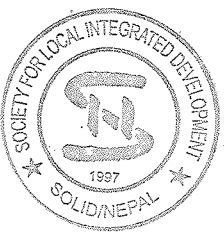
SAE summary

1001	10
1002	6
1003	12
Death Cases	8



Case No.	Site	Subject ID	Relation to the fetus	Pregnancy outcome	Latest contact
1001	1	1001	100100301 Mother	Full term delivery on 23 Sept 2023	12 month postpartum, Both mother and child are normal.
	2	1001	100100507 Mother	Induced/Elective abortion on 26 Jan 2023	-
	3	1001	100100886 Mother	Full term delivery on 28 Sept 2023	12 month postpartum, Both mother and child are normal.
	4	1001	100100609 Mother	No follow-up of outcome	Despite multiple attempts, Unable to contact the participant.
	5	1001	100101210 Mother	Induced/Elective abortion on 18 Mar 2023	-
	6	1001	100101375 Mother	False positive pregnancy	-
	7	1001	100101871 Mother	Full term delivery on 13 Dec 2023	Despite multiple attempts, Unable to contact the participant.
	8	1001	100101796 Mother	Induced/Elective on 12 Apr 2023	-
	9	1001	100102514 Mother	Full term delivery on 6 Dec 2023	Despite multiple attempts, Unable to contact the participant.
	10	1001	100102789 Mother	False positive pregnancy	-
	11	1001	100102897 Mother	False positive pregnancy	-
	12	1001	100100332 Father	Postmature delivery on 6 dec 2023	9 month postpartum, Both mother and child are normal. No congenital malfunction or birth defects.
	13	1001	100102467 Father	No follow-up of outcome	Despite multiple attempts, Unable to contact the participant.
	14	1001	100100329 Father	Induced/elective abortion on 27 May 2023	-
	15	1001	100101063 Mother	Full term delivery on 21 Feb 2023	6 month postpartum, Both mother and child are normal. No congenital malfunction or birth defects.
	16	1001	100103009 Mother	Induced/elective abortion on 16 July 2023	-
	17	1001	100101929 Mother	Induced/elective abortion on 15 Aug 2023	-
	18	1001	100102112 Father	Full term delivery on 2 Jan 2024	8 month postpartum, Both mother and child are normal. No congenital malfunction or birth defects.
1002	1	1002	100200860 Mother	Induced/Elective abortion (17 March 2023)	-
	2	1002	100200739 Mother	Induced/Elective abortion (9 April 2023)	-
	3	1002	100201896 Mother	Induced/Elective abortion (10 May 2023)	-
	4	1002	100201359 Father	No follow-up of outcome	Despite multiple attempts, Unable to contact the participant.
	5	1002	100201239 Mother	No follow-up of outcome	Despite multiple attempts, Unable to contact the participant.
1003	1	1003	100300664 Mother	Induced/Elective abortion (13 April 2023)	-
	2	1003	100301233 Mother	Induced/Elective abortion (13 April 2023)	-
	3	1003	100301327 Father	No follow-up of outcome	Despite multiple attempts, Unable to contact the participant.

- 5 No Follow-up of outcome
- 6 Full term Delivery
- 11 Induced/Elective abortion
- 3 False pregnancy
- 1 Postmature Delivery



Annex IV

A global phase III clinical trial of the recombinant two component COVID-19 vaccine (CHO cells) in adults aged 18 years and above [Recov]

A global phase III clinical trial of the recombinant two component COVID-19 vaccine (CHO cells) in adults aged 18 years and above [Recov]

अध्ययन प्रयोजनका लागि ल्याइएको प्रयोग हुन बाँकी रहेको खोप धुलिकरण

प्रतिवेदन २०८०

नेपाल सरकार

स्वास्थ्य तथा जनसङ्ख्या मन्त्रालय

औषधि व्यवस्था विभाग

बबरमहल, काठमाडौं ।

प्रतिवेदन पेश गर्ने

स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल)

फोन — ०१-५१५१६५६, ०१-५१५१८५५

ईमेल: solidnepal@wlink.com.np

वेब साइट www.solidnepal.org.np

कात्तिक २०८०



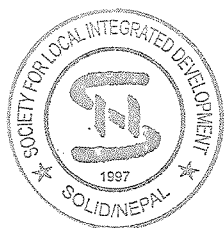
१. अध्ययन खोपको परिचय

चीनको Jiangsu Recbio Technology Co., Ltd. ले विकास गरेको कोभिड-१९ विरुद्धको the recombinant two-component COVID-19 vaccine (CHO cell) को तेस्रो चरणको क्लिनिकल परीक्षण नेपालमा भइरहेको छ । यो खोपको पहिलो र दोस्रो चरणको अनुसन्धानहरू चीनमा नै सम्पन्न भएका छन् । ती अनुसन्धानहरूको नतिजा हेर्दा यो खोप मानव समुदायमा प्रयोग गर्न योग्य छ यो खोप ३ मात्रामा लगाइन्छ । पहिलो खोप लगाएको २१ दिनमा दोस्रो खोप र ४२ दिनमा तेस्रो खोप दिइन्छ । यो खोप पनि चलनचल्तीमा रहेका अन्य खोप जस्तै गरी तयार गरिएको हो । यसमा कोभिड-१९ को भाइरस नहुने भएकाले खोप लगाएपछि कोभिड-१९ सङ्क्रमण हुने डर हुँदैन ।

नेपाल सरकार स्वास्थ्य तथा जनसङ्ख्या मन्त्रालय अन्तर्गत नेपाल स्वास्थ्य अनुसन्धान परिषद्ले यो अध्ययन अनुसन्धानको लागि मिति २०७९ असोज १४ गते तदनुसार ई.स. ३० सेप्टेम्बर २०२२ मा र औषधी व्यवस्था विभागले मिति २०७९ कात्तिक ०३ गते तदनुसार २० अक्टोबर २०२२ मा यो खोप (CHO Cell) परीक्षणको स्वीकृती दिइ समुदायमा खोप लगाउनका लागि ईजाजत दिएको थियो । तेस्रो चरणको विश्वव्यापी अनुसन्धान गर्नका लागि जियाङ्सु रेकबायो टेक्नोलोजी कम्पनी लिमिटेडको CRO को रूपमा MSR Beijing ले नेपालका लागि साझेदार संस्थाको रूपमा स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल) सँग अनुसन्धान परियोजनाको सम्झौता गरेको थियो ।

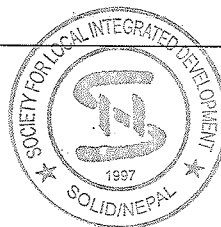
सोलिड नेपालले झापाको भद्रपुरस्थित प्रादेशिक अस्पताल भद्रपुरका मे. सू. डा. टंकप्रसाद बाराकोटी, धरानको बिपि कोईराला स्वास्थ्य विज्ञान प्रतिष्ठान धरानका प्रा. डा. सञ्जीव कुमार शर्मा र काठमाडौंको मनमोहन स्मृति स्वास्थ्य विज्ञान प्रतिष्ठान तथा शिक्षण अस्पताल स्वयम्भुका तत्कालिन मे.सू. डा. केदार प्रसाद सेन्चुरीसँग यो अनुसन्धान परियोजना कार्यान्वयन गर्ने गरी छुट्टाछुट्टै Clinical Trial Agreement (CTA) गरेको थियो । यसै CTA का आधारमा तीनवटै अस्पतालहरूबाट मिति २०७९ मङ्सिर ९ गते शुक्रबार तदनुसार २५ नोभेम्बर २०२२ देखि मिति २०८० जेठ १४ गते आइतबार तदनुसार २८ मे २०२३ सम्ममा जम्मा ४६०७ जनालाई यो अध्ययन खोप लगाइएको थियो ।

जियाङ्सु रेकबायो टेक्नोलोजी कम्पनी लिमिटेडबाट मिति ८ नोभेम्बर २०२२ र मिति १४ फेब्रुअरी २०२३ मा आएको जम्मा १४,४०० मात्रा खोप मध्ये बाँकी रहेका १,१९४ डोज ललितपुर जिल्ला ललितपुर महानगरपालिका वडा नं ३ स्थित नक्खु सेन्ट्रल डिपोमा सुरक्षित रूपमा भण्डारण गरिएको थियो ।



नेपालमा गरिएको यस खोपको तेश्रो चरणको अनुसन्धानको संक्षिप्त विवरण यसप्रकार छ।

अध्ययन शीर्षक	१८ वर्ष वा सोभन्दा माथिका वयस्कहरूमा पुनः संयोजक दुई-कम्पोनेन्ट COVID-19 खोप (CHO सेल) को प्रभावकारिता, सुरक्षा र इम्युनोजेनिसिटी मूल्याङ्कन गर्नको लागि विश्वव्यापी बहुकेन्द्र, रेन्डम, डबल ब्लाइन्ड, प्लेसेबो नियन्त्रित तेश्रो चरणको क्लिनिकल अध्ययन
प्रोटोकल नम्बर	REC611C303
चरण	Phase III तेश्रो चरण
विश्वव्यापी प्रायोजक	Jiangsu Recbio Technology Co., Ltd. A217, Vaccine Engineering Center, 28 Xinglin Road, China Medical City, Taizhou 225316, Jiangsu Province, China
CRO	MSR (Beijing) Pharmaceutical consulting company Ltd , China
बहुराष्ट्रिय क्लिनिकल परीक्षण प्रमुख	Dr. Zhaojun Mo, Principal Investigator, Guangxi Center for Disease Prevention and Control, China
स्थानीय साझेदार संस्था	स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल) सातदोबाटो, ललितपुर नेपाल
नेपालको लागि प्रमुख अनुसन्धानकर्ता	डा. खेम बहादुर कार्की
नेपालको लागि सह अनुसन्धानकर्ता	डा. कृष्ण गोपाल महर्जन डा. अच्युत राज कार्की
नेपालको लागि स्थानीय अनुसन्धानकर्ता	डा. टंकप्रसाद बाराकोटी, प्रादेशिक अस्पताल भद्रपुर, झापा प्रा.डा. सञ्जीव कुमार शर्मा, बिपि कोइराला स्वास्थ्य विज्ञान प्रतिष्ठान धरान डा. केदार प्रासाद सेन्चुरी, मनमोहन मेमोरियल मेडिकल कलेज तथा शिक्षण अस्पताल, स्वयम्भु काठमाडौं ।



२. खोप धुलिकरण निर्देशिका

स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल) ले चीनको ज्याङ्सु रेकबायो टेक्नोलोजी कम्पनी लि. ले विकास गरेको कोभिड-१९ विरुद्धको खोप (CHO Cell) को तेस्रो चरणको क्लिनिकल परीक्षण नेपालमा गरिरहेको छ। यसक्रममा नेपाल आएका १४४०० डोज खोप मध्ये प्रयोग गरेर बाँकी रहेका ११९४ डोज खोपलाई विश्व स्वास्थ्य संगठनको खोप व्यवस्थापन निर्देशिका, नेपाल सरकारको स्वास्थ्य उपचारका फोहर व्यवस्थापन निर्देशिका अनुसार नै सोलिड नेपालले खोप व्यवस्थापन निर्देशिका तयार गरेको छ। यसलाई नेपालका प्रमुख अनुसन्धानकर्ता डा. खेम बहादुर कार्कीले हस्ताक्षर गरी अनुमोदन गर्नु भएको छ। यही निर्देशिकाको अधिनमा रहेर बाँकी रहेका ११९४ मात्रा खोपहरूलाई धुलिकरण गरियो।

३. धुलिकरणको विधि

यस निर्देशिका अनुसार बाँकी रहेका खोपको व्यवस्थापन निम्न अनुसार विधिबाट हुने छ। निर्देशिका यसैसाथ संलग्न छ।

- बाँकी रहेका सबै ११९४ डोज (भाइल)भ्याक्सिनहरूलाई नखुक्नुमा रहेको Central Pharmacy को Cold Store बाट बाहिर निकालियो। भ्याक्सिन बट्टाहरूलाई गाडीमा राखेर धुलिकरण गरिने स्थल मनमोहन अस्पताल, दहचोक काठमाडौंमा लगियो।
- सबै भ्याक्सिन भाइलहरूलाई बट्टाबाट बाहिर निकालियो।
- भाइलमा टाँस गरिएको लेबल हटाइयो।
- यी भाइलहरूलाई प्लास्टिकको ड्रममा भर्दै गइयो।
- ड्रमको तीन चौथाई भाग भरिएपछि बाँकी भाग माटो र सिमेन्टले भरियो।
- सबै बाँकी रहेका भ्याक्सिन भाइलहरूलाई प्लास्टिकको ड्रममा यसैगरी भरीसके पछि त्यसलाई मनमोहन मेमोरियल अस्पताल, दहचोकमा कोभिड अस्पताल सञ्चालनका समयमा बनाईएको कोभिड-१९ जन्य फोहर तथा वस्तुहरू सुरक्षित व्यवस्थापन गर्न बनाइएको पिटमा अझ गहिरो खनेर खाडल बनाइयो।
- उक्त खाडलमा भ्याक्सिन भरिएको ड्रमलाई राखियो। त्यसलाई माथिबाट माटोले पुरियो।



- अस्पतालमा रहेको यो पिट कोभिडको समयमा निर्माण गरिएको, तारबार लगाईएको, नजिकै मनाव वस्ती तथा खेतीयोग्य जमिन नभएको अस्पतालको कम्पाउण्डभित्रै रहेको छ। साथै यो पिटलाई सुरक्षित ढकनीको व्यवस्था पनि गरिएको छ।
- यसरी व्यवस्थापन गरिएको भ्याक्सिन भाइलहरूको मुचुल्का तयार गरी साक्षी रोहबरहरूको सहीछाप गराइयो।
- खोप व्यवस्थापन प्रक्रियाको आवश्यक फोटो तथा भिडियो पनि खिचियो। सबै प्रक्रियाहरू पुरा गरीसकेपछि कार्य सम्पन्न प्रतिवेदन तयार गरियो ।

साक्षी रोहबरमा, मनमोहन मेमोरियल अस्पताल दहचोकका प्रतिनिधि, MSR Beijing का प्रतिनिधि, सोलिड नेपालका प्रतिनिधि रहेका छन् ।



A global phase III clinical trial of the recombinant two component COVID-19 vaccine (CHO cells) in adults aged 18 years and above [Recov]

अनुसूची १ - खोप धुलिकरण निर्देशिका



STANDARD OPERATING PROCEDURE (SOP) of Unused COVID-19 Vaccines Destruction

Author	Mr. Ajit Acharya Clinical Research Project Coordinator	Signature/Date:  8-Dec-2022
Reviewed by	Ms. Dina Pradhan Acting Executive Director	Signature/Date:  9 Dec 2022
Approved by	Dr. Khem Bahadur Karki Country PI	Signature/Date:  10 Dec. 2022



Developed and Approved by

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2022

Kathmandu, Nepal



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1. Glossary

COVID-19:	CORONA VIRUS Diseases.
HCF:	Health Care Facility
HCWM:	Health Care Waste Management.
PPE:	Personal Protective Equipment.
SOP:	Standard Operational Procedure.

2. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the detailed process on how to manage unused COVID-19 vaccine after COVID-19 vaccination activities end. The SOP provides clear instructions on how to perform the appropriate treatment and safe disposal of these unused vaccines to minimize any associated health risks with consideration of the local context.

3. Scope

This SOP is intended for staff involved in the unused COVID-19 vaccine destruction activity and covers the procedures of the final destruction and disposal of the unused vaccine.

4. Principles

Unused COVID-19 vaccine is considered infectious material, and they must be correctly and safely collected, stored, transported, and disposed of, under the supervision of well-trained staff or HCWM specialist technicians.

Prior to the launch of COVID-19 vaccine destruction activities, the responsible person should ensure that standard management procedures are always correctly applied, and the supporting infrastructures are available and functional.

5. Procedures

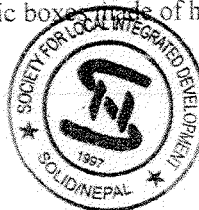
The unused COVID-19 vaccine can be adequately disposed of/destroyed by the following two methods. During the destruction process, relevant records shall be made, at least including the time, place and method of destruction, name and quantity of vaccine, the destructor, supervisor and photos of destruction process, etc.

5.1 Burial-based disposal methods

Burial of waste is one of the oldest and popular techniques of waste/vaccine disposal. There are many ways of burial; some of which are summarized below:

5.1.1 Encapsulation

Encapsulation involves filling of the containers with vaccines, adding an immobilizing material and sealing the container. The process uses either cubic boxes or a pile of high-density



polyethylene or metallic drum. When containers are three-quarters filled with the vaccines, immobilizing agent such as plastic foam, bituminous sand, cement mortar or clay is poured into it. The material dries and the container is sealed and disposed of safely in the landfill. Encapsulation is effective in reducing the risk of scavengers gaining access to hazardous waste.

5.1.2 Inertization

Inertization is a suitable disposal method of pharmaceutical and incinerated ashes with heavy metal content. In this technique the vaccine is mixed with cement and other substances in a composition of 65% vaccine, 15% lime, 15% cement and 5% water. The formed mixture is allowed to set into cubes or pellets, the waste must be grinded. This technique helps to minimize the risk of contamination of toxic substances through migration to surface water or groundwater and prevent scavenging.

5.2 Sanitary landfill

Sanitary landfill is an engineered method and constructed to keep the vaccine isolated from the environment. There should not be any contamination of the soil, surface, and groundwater. Furthermore, it should limit air pollution, smells and direct contact with the public. Some essential features of sanitary landfills are:

- The site should be planned appropriately before starting the landfill. Landfill site should be at least 500 meters away from water sources.
- Lining of the base and sides of the sites must be adequately sealed to minimize the movement of wastewater.
- There must be landfill gas control measures, environmental monitoring points and bore holes (for monitoring air and groundwater quality).
- There must be adequate and efficient mechanisms for leachate collection and treatment.
- The landfill site must be protected with wire bar or fences to prevent from unauthorized access by people and animals.
- Final cover must be constructed to prevent and minimize rainwater infiltration after the landfill is completed.

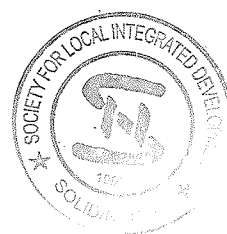
6. Emergency response in case of spillage

Spillage is the most common type of emergency involving infectious and other hazardous materials. Spills are inadvertent discharges that occur at different places of HCF, include accidental tipping over containers, dropping and breaking of containers. The response process for the spillage includes:

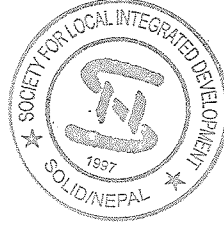
- Evacuation of the contaminated area.
- Informing immediate supervisor for the further action.
- Neutralization or disinfection for the contaminated materials and area. The decontamination should be carried out by working from the least to the most contaminated part. Dry cloth should be used in case of liquid spillage. Appropriate PPE should be worn before the clean up process.
- In case of skin contamination with hazardous substances, immediate decontamination needs to take place by washing.
- Keep relevant records of spillage case.



अनुसूची २ - खोप धुलिकरण गर्दाको समयको मुचुल्का



अनुसूची ३ - अध्ययन खोपसम्बन्धी कागजातहरू



लिखितम हामी तपशिलमा नाम थर वतन लेखिएका व्यक्तिहरू आगे स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल) ले चीनको Jiangsu Recbio Technology Co., Ltd. ले विकास गरेको कोभिड-१९ विरुद्धको the recombinant two-component COVID-19 vaccine (CHO cell) को तेस्रो चरणको क्लिनिकल परीक्षण नेपालको झापा स्थित प्रादेशिक अस्पताल भद्रपुर, धरान स्थित विपि कोइराला मेमोरियल अस्पताल धरान र काठमाडौं स्थित मनमोहन मेमोरियल अस्पतालसँग सहकार्य गरी सञ्चालन भइरहेकोमा उपर्युक्त कम्पनीबाट प्राप्त अनुसन्धान खोप (Investigational Product) मध्ये बाँकी रहेका ११९४ डोज अनुसन्धान खोप ललितपुर जिल्ला ललितपुर महानगरपालिका वडा नं ३ स्थित नक्खु सेन्ट्रल डिपोमा सुरक्षित रूपमा भण्डारण गरिएकोमा उल्लिखित सबै अध्ययन खोपहरू भण्डार गरिएको ठाउँबाट बाहिर निकाली, टाँस गरिएको सबै विवरणहरू हटाई, प्लाष्टिकको ड्रममा राखी, ड्रमको तीन चौथाई भाग भरिएपछि बाँकी भाग माटो, बालुवा र सिमेन्टले भरी मनमोहन मेमोरियल अस्पताल दहचोक, काठमाडौंमा सुरक्षित खाडल खनि खाडलमा भ्याक्सिन सहितको ड्रमलाई राखी त्यसमाथि माटोले पुरी छोपेको कुरा हामीहरूले प्रत्यक्ष रूपमा देखेका हौं। उक्त कार्य हाम्रो रोहबरमा गरिएको ठिक साँचो हो ।

रोहवर

MSR Beijing का श्री करिना महर्जन

.....

MSR Beijing का श्री स्वेता लम्साल

.....

सोलिड नेपालका श्री अजित आचार्य

.....

मनमोहन अस्पताल, दहचोकका डा. आर्यन दहाल

.....

मनमोहन अस्पताल, दहचोकका श्री रामकृष्ण श्रेष्ठ

.....

इति सम्बत् २०८० साल कात्तिक २४ गते रोज ६ शुभम ।



IP Destruction Form (Site)

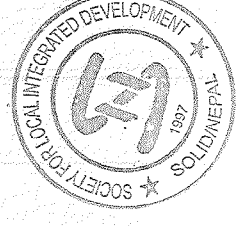
Sponsor	Jiangsu Recbio Technology Co., Ltd.	Protocol No.	REC611C303
Site Name	Manmohan Memoria Medical College and Teaching Hospital (MMMCTH)	Site No.	1003

Method of destruction	Container packaging and Landfill		
Total quantity of units (small box) to be destroyed	2831		
Destruction company Name and personnel	MMMCTH, <name of the site staff>	signature and date	
Witness Name		Witness signature and date	

Commented [A1]: Name of site staff involved in the destruction

Commented [A2]: The hospital can invite a witness for the process who is not related to the study site

Vaccine number	Used Vials (please, specify vial numbers, if applicable)	Partial Vials (please, specify vial numbers, if applicable)	Exact quantity of units destroyed	Batch number	Expiry date	Initial & Date
9000801 - 9001000	200	NA	200	TC202205002/TC202207001	29-Apr-2023	
9001301 - 9001363	63	NA	63	TC202205002/TC202207001	29-Apr-2023	
9001365 - 9001495	131	NA	131	TC202205002/TC202207001	29-Apr-2023	
9001497 - 9001700	204	NA	204	TC202205002/TC202207001	29-Apr-2023	
9002301 - 9002417	117	NA	117	TC202205002/TC202207001	29-Apr-2023	
9002419 - 9002559	141	NA	141	TC202205002/TC202207001	29-Apr-2023	
9002561 - 9002627	67	NA	67	TC202205002/TC202207001	29-Apr-2023	
9002629 - 9002700	72	NA	72	TC202205002/TC202207001	29-Apr-2023	
9004101 - 9004207	107	NA	107	TC202205002/TC202207001	29-Apr-2023	
9004209 - 9004500	292	NA	292	TC202205002/TC202207001	29-Apr-2023	



IP Destruction Form (Site)

Sponsor	Jiangsu Recbio Technology Co., Ltd.	Protocol No.	REC611C303
Site Name	Manmohan Memorial Medical College and Teaching Hospital (MMMCTH)	Site No.	1003

Vaccine number	Used Vials		Partial Vials (please specify vial numbers, if applicable)	Exact quantity of units destroyed	Batch number	Expiry date	Initial & Date
	(please specify vial numbers, if applicable)						
9006401 - 9006576	176		NA	176	TC202205002/TC202207001	29-Apr-2023	
9006578 - 9006800	223		NA	223	TC202205002/TC202207001	29-Apr-2023	
9007601 - 9007805	205		NA	205	TC202205002/TC202207001	29-Apr-2023	
9007807 - 9008000	194		NA	194	TC202205002/TC202207001	29-Apr-2023	
9008801 - 9008925	125		NA	125	TC202205002/TC202207001	29-Apr-2023	
9008927 - 9009200	274		NA	274	TC202205002/TC202207001	29-Apr-2023	
9011601 - 9011646	46		NA	46	TC202205002/TC202207001	29-Apr-2023	
9011648 - 9011822	175		NA	175	TC202205002/TC202207001	29-Apr-2023	
9011825, 9011826, 9011830, 9011832, 9011835, 9011836, 9011837, 9011838, 9011842, 9011843, 9011846, 9011849, 9011850, 9011851, 9011853, 9011854, 9011856, 9011860, 9011861	19		NA	19	TC202205002/TC202207001	29-Apr-2023	



2022-11-01 (10/11/2022)

Vaccine number	Used Vials	Partial Vials	Exact quantity of units destroyed	Batch number	Expiry date	Initial & Date
	(please, specify vial numbers, if applicable)	(please, specify vial numbers, if applicable)				
9006401 - 9006576	176		176	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9006578 - 9006800	223	NA	223	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9007601 - 9007805		NA		TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9007807 - 9008000	205	NA	205	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9008801 - 9008925	194	NA	194	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9008927 - 9009200	125	NA	125	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9011601 - 9011646	274	NA	274	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9011648 - 9011822	46	NA	46	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
9011825, 9011826, 9011830, 9011832, 9011835, 9011836, 9011837, 9011838, 9011842, 9011843, 9011846, 9011849, 9011850, 9011851, 9011853, 9011854, 9011856, 9011860, 9011861	175	NA	175	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023
	19		19	TC202205002/TC202207001	29-Apr-2023	12-0-C 10-Nov-2023



Method of destruction

Total quantity of units (small box) to be destroyed

Container packaging, encapsulation and Landfill

2831

Destruction company Name and personnel

MMIMCTH,
Dr. Kedar P. Cerntury.

signature and date

[Signature]
10/Nov/2023

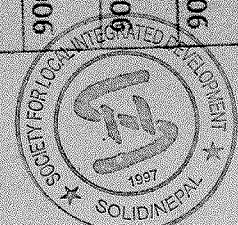
Witness Name

Mr. Anuradha (Gurav)

Witness signature and date

[Signature]

Vaccine number	Used Vials (please, specify vial numbers, if applicable)	Partial Vials (please, specify vial numbers, if applicable)		Exact quantity of units destroyed	Batch number	Expiry date	Initial & Date
9000801 - 9001000	200	NA	NA	200	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9001301 - 9001363	63	NA	NA	63	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9001365 - 9001495	131	NA	NA	131	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9001497 - 9001700	204	NA	NA	204	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9002301 - 9002417	117	NA	NA	117	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9002419 - 9002559	141	NA	NA	141	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9002561 - 9002627	67	NA	NA	67	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9002629 - 9002700	72	NA	NA	72	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9004101 - 9004207	107	NA	NA	107	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023
9004209 - 9004500	292	NA	NA	292	TC202205002/TC202207001	29-Apr-2023	K-P-C 10-Nov-2023



List of IP (Unused) for Destruction

1	9003571	53	9013346	105	9013398	157	9013450
2	9003572	54	9013347	106	9013399	158	9000627
3	9003573	55	9013348	107	9013400	159	9000647
4	9003574	56	9013349	108	9013401	160	9000738
5	9003575	57	9013350	109	9013402	161	9002030
6	9003576	58	9013351	110	9013403	162	9003034
7	9003577	59	9013352	111	9013404	163	9003335
8	9003578	60	9013353	112	9013405	164	9013293
9	9003579	61	9013354	113	9013406	165	9013296
10	9003580	62	9013355	114	9013407	166	9013314
11	9010665	63	9013356	115	9013408	167	9013537
12	9013298	64	9013357	116	9013409	168	9013539
13	9013299	65	9013358	117	9013410	169	9013545
14	9013302	66	9013359	118	9013411	170	9013546
15	9013304	67	9013360	119	9013412	171	9013548
16	9013305	68	9013361	120	9013413	172	9013549
17	9013308	69	9013362	121	9013414	173	9013550
18	9013309	70	9013363	122	9013415	174	9013551
19	9013311	71	9013364	123	9013416	175	9013552
20	9013312	72	9013365	124	9013417	176	9013557
21	9013313	73	9013366	125	9013418	177	9013559
22	9013315	74	9013367	126	9013419	178	9013560
23	9013316	75	9013368	127	9013420	179	9013561
24	9013317	76	9013369	128	9013421	180	9013563
25	9013318	77	9013370	129	9013422	181	9013566
26	9013319	78	9013371	130	9013423	182	9013567
27	9013320	79	9013372	131	9013424	183	9013570
28	9013321	80	9013373	132	9013425	184	9013573
29	9013322	81	9013374	133	9013426	185	9013574
30	9013323	82	9013375	134	9013427	186	9013576
31	9013324	83	9013376	135	9013428	187	9013577
32	9013325	84	9013377	136	9013429	188	9013579
33	9013326	85	9013378	137	9013430	189	9013580
34	9013327	86	9013379	138	9013431	190	9013581
35	9013328	87	9013380	139	9013432	191	9013582
36	9013329	88	9013381	140	9013433	192	9013583
37	9013330	89	9013382	141	9013434	193	9013584
38	9013331	90	9013383	142	9013435	194	9013585
39	9013332	91	9013384	143	9013436	195	9013586
40	9013333	92	9013385	144	9013437	196	9013587
41	9013334	93	9013386	145	9013438	197	9013588
42	9013335	94	9013387	146	9013439	198	9013589
43	9013336	95	9013388	147	9013440	199	9013590
44	9013337	96	9013389	148	9013441	200	9013591
45	9013338	97	9013390	149	9013442	201	9013592
46	9013339	98	9013391	150	9013443	202	9013593
47	9013340	99	9013392	151	9013444	203	9013594
48	9013341	100	9013393	152	9013445	204	9013595
49	9013342	101	9013394	153	9013446	205	9013596
50	9013343	102	9013395	154	9013447	206	9013597
51	9013344	103	9013396	155	9013448	207	9013601
52	9013345	104	9013397	156	9013449	208	9013602



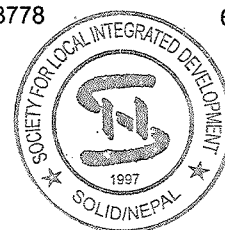
List of IP (Unused) for Destruction

209	9013603	261	9013634	313	9013669	365	9011940
210	9013604	262	9013635	314	9013670	366	9011941
211	9013605	263	9013636	315	9013671	367	9011942
212	9013606	264	9013637	316	9013672	368	9011943
213	9013607	265	9013638	317	9013673	369	9011944
214	9013608	266	9013639	318	9013674	370	9011945
215	9013609	267	9013640	319	9013675	371	9011946
216	9013610	268	9013700	320	9013676	372	9011947
217	9013611	269	9003774	321	9013677	373	9011948
218	9013612	270	9003771	322	9013678	374	9011949
219	9013613	271	9003773	323	9013679	375	9011950
220	9013614	272	9003775	324	9013680	376	9011951
221	9013615	273	9003776	325	9013681	377	9011952
222	9013616	274	9003777	326	9011901	378	9011953
223	9013617	275	9003778	327	9011902	379	9011954
224	9013618	276	9003779	328	9011903	380	9011955
225	9013619	277	9003262	329	9011904	381	9011956
226	9013600	278	9003772	330	9011905	382	9011957
227	9013641	279	9009268	331	9011906	383	9011958
228	9013642	280	9009792	332	9011907	384	9011959
229	9013690	281	9011353	333	9011908	385	9011960
230	9013691	282	9013683	334	9011909	386	9011961
231	9013692	283	9013684	335	9011910	387	9011962
232	9013693	284	9013685	336	9011911	388	9011963
233	9013694	285	9013686	337	9011912	389	9011964
234	9013695	286	9013682	338	9011913	390	9011965
235	9013696	287	9013643	339	9011914	391	9011966
236	9013697	288	9013644	340	9011915	392	9011967
237	9013698	289	9013645	341	9011916	393	9011968
238	9013699	290	9013646	342	9011917	394	9011969
239	9003780	291	9013647	343	9011918	395	9011970
240	9000261	292	9013648	344	9011919	396	9011971
241	9000468	293	9013649	345	9011920	397	9011972
242	9013687	294	9013650	346	9011921	398	9011973
243	9013688	295	9013651	347	9011922	399	9011974
244	9013689	296	9013652	348	9011923	400	9011975
245	9013598	297	9013653	349	9011924	401	9011976
246	9013599	298	9013654	350	9011925	402	9011977
247	9013620	299	9013655	351	9011926	403	9011978
248	9013621	300	9013656	352	9011927	404	9011979
249	9013622	301	9013657	353	9011928	405	9011980
250	9013623	302	9013658	354	9011929	406	9011981
251	9013624	303	9013659	355	9011930	407	9011982
252	9013625	304	9013660	356	9011931	408	9011983
253	9013626	305	9013661	357	9011932	409	9011984
254	9013627	306	9013662	358	9011933	410	9011985
255	9013628	307	9013663	359	9011934	411	9011986
256	9013629	308	9013664	360	9011935	412	9011987
257	9013630	309	9013665	361	9011936	413	9011988
258	9013631	310	9013666	362	9011937	414	9011989
259	9013632	311	9013667	363	9011938	415	9011990
260	9013633	312	9013668	364	9011939	416	9011991



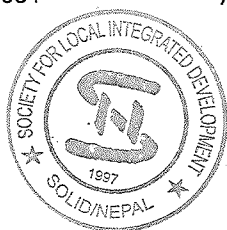
List of IP (Unused) for Destruction

417	9011992	469	9011875	521	9013727	573	9013779
418	9011993	470	9011876	522	9013728	574	9013780
419	9011994	471	9011877	523	9013729	575	9013781
420	9011995	472	9011878	524	9013730	576	9013782
421	9011996	473	9011879	525	9013731	577	9013783
422	9011997	474	9011880	526	9013732	578	9013784
423	9011998	475	9011881	527	9013733	579	9013785
424	9011999	476	9011882	528	9013734	580	9013786
425	9012000	477	9011883	529	9013735	581	9013787
426	9011859	478	9011884	530	9013736	582	9013788
427	9011858	479	9011885	531	9013737	583	9013789
428	9011840	480	9011886	532	9013738	584	9013790
429	9002560	481	9011887	533	9013739	585	9013791
430	9011852	482	9011888	534	9013740	586	9013792
431	9011823	483	9011889	535	9013741	587	9013793
432	9011869	484	9011890	536	9013742	588	9013794
433	9011833	485	9011891	537	9013743	589	9013795
434	9011834	486	9011892	538	9013744	590	9013796
435	9011845	487	9011893	539	9013745	591	9013797
436	9011866	488	9011894	540	9013746	592	9013798
437	9011827	489	9011895	541	9013747	593	9013799
438	9011865	490	9011896	542	9013748	594	9013800
439	9002418	491	9011897	543	9013749	595	9013801
440	9006577	492	9011898	544	9013750	596	9013802
441	9011848	493	9011899	545	9013751	597	9013803
442	9011857	494	9011900	546	9013752	598	9013804
443	9011831	495	9013701	547	9013753	599	9013805
444	9011829	496	9013702	548	9013754	600	9013806
445	9008926	497	9013703	549	9013755	601	9013807
446	9011844	498	9013704	550	9013756	602	9013808
447	9011647	499	9013705	551	9013757	603	9013809
448	9011868	500	9013706	552	9013758	604	9013810
449	9011824	501	9013707	553	9013759	605	9013811
450	9011828	502	9013708	554	9013760	606	9013812
451	9011863	503	9013709	555	9013761	607	9013813
452	9011862	504	9013710	556	9013762	608	9013814
453	9011870	505	9013711	557	9013763	609	9013815
454	9011847	506	9013712	558	9013764	610	9013816
455	9011839	507	9013713	559	9013765	611	9013817
456	9011855	508	9013714	560	9013766	612	9013818
457	9011864	509	9013715	561	9013767	613	9013819
458	9001496	510	9013716	562	9013768	614	9013820
459	9007806	511	9013717	563	9013769	615	9013821
460	9001364	512	9013718	564	9013770	616	9013822
461	9011841	513	9013719	565	9013771	617	9013823
462	9011867	514	9013720	566	9013772	618	9013824
463	9002628	515	9013721	567	9013773	619	9013825
464	9004208	516	9013722	568	9013774	620	9013826
465	9011871	517	9013723	569	9013775	621	9013827
466	9011872	518	9013724	570	9013776	622	9013828
467	9011873	519	9013725	571	9013777	623	9013829
468	9011874	520	9013726	572	9013778	624	9013830



List of IP (Unused) for Destruction

625	9013831	677	9013883	729	9013935	781	9013987
626	9013832	678	9013884	730	9013936	782	9013988
627	9013833	679	9013885	731	9013937	783	9013989
628	9013834	680	9013886	732	9013938	784	9013990
629	9013835	681	9013887	733	9013939	785	9013991
630	9013836	682	9013888	734	9013940	786	9013992
631	9013837	683	9013889	735	9013941	787	9013993
632	9013838	684	9013890	736	9013942	788	9013994
633	9013839	685	9013891	737	9013943	789	9013995
634	9013840	686	9013892	738	9013944	790	9013996
635	9013841	687	9013893	739	9013945	791	9013997
636	9013842	688	9013894	740	9013946	792	9013998
637	9013843	689	9013895	741	9013947	793	9013999
638	9013844	690	9013896	742	9013948	794	9014000
639	9013845	691	9013897	743	9013949	795	9014001
640	9013846	692	9013898	744	9013950	796	9014002
641	9013847	693	9013899	745	9013951	797	9014003
642	9013848	694	9013900	746	9013952	798	9014004
643	9013849	695	9013901	747	9013953	799	9014005
644	9013850	696	9013902	748	9013954	800	9014006
645	9013851	697	9013903	749	9013955	801	9014007
646	9013852	698	9013904	750	9013956	802	9014008
647	9013853	699	9013905	751	9013957	803	9014009
648	9013854	700	9013906	752	9013958	804	9014010
649	9013855	701	9013907	753	9013959	805	9014011
650	9013856	702	9013908	754	9013960	806	9014012
651	9013857	703	9013909	755	9013961	807	9014013
652	9013858	704	9013910	756	9013962	808	9014014
653	9013859	705	9013911	757	9013963	809	9014015
654	9013860	706	9013912	758	9013964	810	9014016
655	9013861	707	9013913	759	9013965	811	9014017
656	9013862	708	9013914	760	9013966	812	9014018
657	9013863	709	9013915	761	9013967	813	9014019
658	9013864	710	9013916	762	9013968	814	9014020
659	9013865	711	9013917	763	9013969	815	9014021
660	9013866	712	9013918	764	9013970	816	9014022
661	9013867	713	9013919	765	9013971	817	9014023
662	9013868	714	9013920	766	9013972	818	9014024
663	9013869	715	9013921	767	9013973	819	9014025
664	9013870	716	9013922	768	9013974	820	9014026
665	9013871	717	9013923	769	9013975	821	9014027
666	9013872	718	9013924	770	9013976	822	9014028
667	9013873	719	9013925	771	9013977	823	9014029
668	9013874	720	9013926	772	9013978	824	9014030
669	9013875	721	9013927	773	9013979	825	9014031
670	9013876	722	9013928	774	9013980	826	9014032
671	9013877	723	9013929	775	9013981	827	9014033
672	9013878	724	9013930	776	9013982	828	9014034
673	9013879	725	9013931	777	9013983	829	9014035
674	9013880	726	9013932	778	9013984	830	9014036
675	9013881	727	9013933	779	9013985	831	9014037
676	9013882	728	9013934	780	9013986	832	9014038



List of IP (Unused) for Destruction

833	9014039	885	9014091	937	9014143	989	9014195
834	9014040	886	9014092	938	9014144	990	9014196
835	9014041	887	9014093	939	9014145	991	9014197
836	9014042	888	9014094	940	9014146	992	9014198
837	9014043	889	9014095	941	9014147	993	9014199
838	9014044	890	9014096	942	9014148	994	9014200
839	9014045	891	9014097	943	9014149	995	9014201
840	9014046	892	9014098	944	9014150	996	9014202
841	9014047	893	9014099	945	9014151	997	9014203
842	9014048	894	9014100	946	9014152	998	9014204
843	9014049	895	9014101	947	9014153	999	9014205
844	9014050	896	9014102	948	9014154	1000	9014206
845	9014051	897	9014103	949	9014155	1001	9014207
846	9014052	898	9014104	950	9014156	1002	9014208
847	9014053	899	9014105	951	9014157	1003	9014209
848	9014054	900	9014106	952	9014158	1004	9014210
849	9014055	901	9014107	953	9014159	1005	9014211
850	9014056	902	9014108	954	9014160	1006	9014212
851	9014057	903	9014109	955	9014161	1007	9014213
852	9014058	904	9014110	956	9014162	1008	9014214
853	9014059	905	9014111	957	9014163	1009	9014215
854	9014060	906	9014112	958	9014164	1010	9014216
855	9014061	907	9014113	959	9014165	1011	9014217
856	9014062	908	9014114	960	9014166	1012	9014218
857	9014063	909	9014115	961	9014167	1013	9014219
858	9014064	910	9014116	962	9014168	1014	9014220
859	9014065	911	9014117	963	9014169	1015	9014221
860	9014066	912	9014118	964	9014170	1016	9014222
861	9014067	913	9014119	965	9014171	1017	9014223
862	9014068	914	9014120	966	9014172	1018	9014224
863	9014069	915	9014121	967	9014173	1019	9014225
864	9014070	916	9014122	968	9014174	1020	9014226
865	9014071	917	9014123	969	9014175	1021	9014227
866	9014072	918	9014124	970	9014176	1022	9014228
867	9014073	919	9014125	971	9014177	1023	9014229
868	9014074	920	9014126	972	9014178	1024	9014230
869	9014075	921	9014127	973	9014179	1025	9014231
870	9014076	922	9014128	974	9014180	1026	9014232
871	9014077	923	9014129	975	9014181	1027	9014233
872	9014078	924	9014130	976	9014182	1028	9014234
873	9014079	925	9014131	977	9014183	1029	9014235
874	9014080	926	9014132	978	9014184	1030	9014236
875	9014081	927	9014133	979	9014185	1031	9014237
876	9014082	928	9014134	980	9014186	1032	9014238
877	9014083	929	9014135	981	9014187	1033	9014239
878	9014084	930	9014136	982	9014188	1034	9014240
879	9014085	931	9014137	983	9014189	1035	9014241
880	9014086	932	9014138	984	9014190	1036	9014242
881	9014087	933	9014139	985	9014191	1037	9014243
882	9014088	934	9014140	986	9014192	1038	9014244
883	9014089	935	9014141	987	9014193	1039	9014245
884	9014090	936	9014142	988	9014194	1040	9014246



List of IP (Unused) for Destruction

1041	9014247	1093	9014299	1145	9014351
1042	9014248	1094	9014300	1146	9014352
1043	9014249	1095	9014301	1147	9014353
1044	9014250	1096	9014302	1148	9014354
1045	9014251	1097	9014303	1149	9014355
1046	9014252	1098	9014304	1150	9014356
1047	9014253	1099	9014305	1151	9014357
1048	9014254	1100	9014306	1152	9014358
1049	9014255	1101	9014307	1153	9014359
1050	9014256	1102	9014308	1154	9014360
1051	9014257	1103	9014309	1155	9014361
1052	9014258	1104	9014310	1156	9014362
1053	9014259	1105	9014311	1157	9014363
1054	9014260	1106	9014312	1158	9014364
1055	9014261	1107	9014313	1159	9014365
1056	9014262	1108	9014314	1160	9014366
1057	9014263	1109	9014315	1161	9014367
1058	9014264	1110	9014316	1162	9014368
1059	9014265	1111	9014317	1163	9014369
1060	9014266	1112	9014318	1164	9014370
1061	9014267	1113	9014319	1165	9014371
1062	9014268	1114	9014320	1166	9014372
1063	9014269	1115	9014321	1167	9014373
1064	9014270	1116	9014322	1168	9014374
1065	9014271	1117	9014323	1169	9014375
1066	9014272	1118	9014324	1170	9014376
1067	9014273	1119	9014325	1171	9014377
1068	9014274	1120	9014326	1172	9014378
1069	9014275	1121	9014327	1173	9014379
1070	9014276	1122	9014328	1174	9014380
1071	9014277	1123	9014329	1175	9014381
1072	9014278	1124	9014330	1176	9014382
1073	9014279	1125	9014331	1177	9014383
1074	9014280	1126	9014332	1178	9014384
1075	9014281	1127	9014333	1179	9014385
1076	9014282	1128	9014334	1180	9014386
1077	9014283	1129	9014335	1181	9014387
1078	9014284	1130	9014336	1182	9014388
1079	9014285	1131	9014337	1183	9014389
1080	9014286	1132	9014338	1184	9014390
1081	9014287	1133	9014339	1185	9014391
1082	9014288	1134	9014340	1186	9014392
1083	9014289	1135	9014341	1187	9014393
1084	9014290	1136	9014342	1188	9014394
1085	9014291	1137	9014343	1189	9014395
1086	9014292	1138	9014344	1190	9014396
1087	9014293	1139	9014345	1191	9014397
1088	9014294	1140	9014346	1192	9014398
1089	9014295	1141	9014347	1193	9014399
1090	9014296	1142	9014348	1194	9014400
1091	9014297	1143	9014349		
1092	9014298	1144	9014350		



Schedule-13
(Relating to Sub-rule (2) of Rule 8)
Government of Nepal
Ministry of Health
Department of Drug Administration
License for clinical trial

Ref no. 1419

This license is hereby issued, setting out the following matters, allowing the following person to conduct clinical trial of the following new drug, subject to the Drug Act, 2035(1978) and the Drug Registration Rules, 2038(1981).

1. Of the new drug licensed for clinical trial:

Name	System	Group	Composition	Type or Kind	Active ingredient's		Remarks
					Name	Quantity	
Covid-19 Vaccine (CHO Cell)	ALLOPATHY	KHA	Recombinant two component Covid-19 Vaccine (CHO Cell)	Vaccine	Covid-19 Vaccine (CHO Cell)	20 µg/Vial	

2. Of the disease licensed for clinical trial:

- (a) **Name:** COVID-19
(b) **Method of diagnosis:** PCR / RAPID TEST BY SWAB

3. Of the consumption of the new drug to be administered in the course of clinical trial:

- (a) **Method:** Intramuscular injection
(b) **Dosage (daily):** 20 µg/Vial, 0.5 ml/Dose, for each dose of vaccination
(c) **Period:** Three dose intramuscular vaccination schedule (Day 0, Day 21 and Day 42)

4. Mode of clinical trial: Randomized, Double Blind, Placebo-Controlled Trial, Phase III Clinical Trial

5. Place where clinical trial is to be conducted: BP Koirala Institute of Health Sciences, Dharan

6. Of the person allowed conducting clinical trial:

- (a) **Name, surname and address:** DR. KHEM BAHADUR KARKI (Principal Investigator)
(b) **Occupation:** DOCTOR
(c) **Qualifications:**

7. Validity period of license: TILL DATE: Sep 30, 2023

License receiver's:

Signature:

Date:

For
Gital
2079/07/03

License issuing officer's:

Signature:

Name: SHIWANI KHADGI

Date: October 20, 2022

Designation: SENIOR DRUG ADMIMISTRATOR



October 20, 2022

***NOTE**

A. NAME OF THE CLINICAL TRIAL:

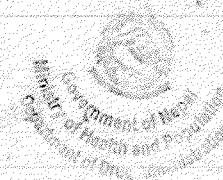
"A multicenter, randomized, double-blind, placebo-controlled, phase III trial to evaluate the efficacy, safety and immunogenicity of the Recombinant two-component COVID-19 Vaccine (CHO Cell) in adults aged 18 years and older"

CONDITION APPLIED:

1. The clinical trial should be conducted as per approved protocol and Good Clinical Practices (GCP).
2. For any variation related to the protocol, application for amendment approval should be submitted to the Department.
3. Notification on the start of the clinical trial should be made to the Department.
4. Ongoing progress report of the clinical trial should be submitted to the Department quarterly.
5. If any Severe adverse effect (SAE), AEFI is observed during this trial, immediate notification should be submitted to the Department.
6. Notification on completion of the clinical trial study and final report should be submitted to the Department.

Dr. Anil

Senior Drug Affairs Officer
10th Level



Schedule-13
(Relating to Sub-rule (2) of Rule 8)
Government of Nepal
Ministry of Health
Department of Drug Administration
License for clinical trial

Ref. No. 1418

This license is hereby issued, setting out the following matters, allowing the following person to conduct clinical trial of the following new drug, subject to the Drug Act, 2035(1978) and the Drug Registration Rules, 2038(1981).

1. Of the new drug licensed for clinical trial:

Name	System	Group	Composition	Type or Kind	Active ingredient's		Remarks
					Name	Quantity	
Covid-19 Vaccine (CHO Cell)	ALLOPATHY	KHA	Recombinant two component Covid-19 Vaccine (CHO Cell)	Vaccine	Covid-19 Vaccine (CHO Cell)	20 µg/Vial	

2. Of the disease licensed for clinical trial:

(a) **Name:** COVID-19

(b) **Method of diagnosis:** PCR / RAPID TEST BY SWAB

3. Of the consumption of the new drug to be administered in the course of clinical trial:

(a) **Method:** Intramuscular injection

(b) **Dosage (daily):** 20 µg/Vial, 0.5 ml/Dose, for each dose of vaccination

(c) **Period:** Three dose intramuscular vaccination schedule (Day 0, Day 21 and Day 42)

4. Mode of clinical trial: Randomized, Double Blind, Placebo-Controlled Trial, Phase III Clinical Trial

5. Place where clinical trial is to be conducted: Manmohan Memorial Medical College and Teaching Hospital, Kathimandu

6. Of the person allowed conducting clinical trial:

(a) **Name, surname and address:** DR. KHEM BAHADUR KARKI (Principal Investigator)

(b) **Occupation:** DOCTOR

(c) **Qualifications:**

7. Validity period of license: **ILL DATE, Sep 30, 2023**

License receiver's:

Signature:

Date:

FOR
Apt
2079/07/03

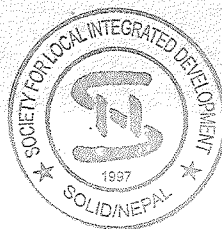
License issuing officer's:

Signature:

Name: SHIWANI KHADGI

Date: October 20, 2022

Designation: SENIOR DRUG ADMIMISTRATOR



October 20, 2022

***NOTE**

A. NAME OF THE CLINICAL TRIAL:

"A multicenter, randomized, double-blind, placebo-controlled, phase III trial to evaluate the efficacy, safety and immunogenicity of the Recombinant two-component COVID-19 Vaccine (CHO Cell) in adults aged 18 years and older"

CONDITION APPLIED:

1. The clinical trial should be conducted as per approved protocol and Good Clinical Practices (GCP).
2. For any variation related to the protocol, application for amendment approval should be submitted to the Department.
3. Notification on the start of the clinical trial should be made to the Department.
4. Ongoing progress report of the clinical trial should be submitted to the Department quarterly.
5. If any Severe adverse effect (SAE), AEFI is observed during this trial, immediate notification should be submitted to the Department.
6. Notification on completion of the clinical trial study and final report should be submitted to the Department.

Omur
Senior Drug Administration
10th Level
Ministry of Health and Population
Department of Drug Administration
Government of Nepal



Schedule-13
(Relating to Sub-rule (2) of Rule 8)
Government of Nepal
Ministry of Health
Department of Drug Administration
License for clinical trial

Ref No. 1420
This license is hereby issued, setting out the following matters, allowing the following person to conduct clinical trial of the following new drug, subject to the Drug Act, 2035(1978) and the Drug Registration Rules, 2038(1981).

1. Of the new drug licensed for clinical trial:

Name	System	Group	Composition	Type or Kind	Active ingredient's		Remarks
					Name	Quantity	
Covid-19 Vaccine (CHO Cell)	ALLOPATHY	KHA	Recombinant two component Covid-19 Vaccine (CHO Cell)	Vaccine	Covid-19 Vaccine (CHO Cell)	20 µg/Vial	

2. Of the disease licensed for clinical trial:

(a) **Name:** COVID-19

(b) **Method of diagnosis:** PCR /Rapid Test By Swab

3. Of the consumption of the new drug to be administered in the course of clinical trial:

(a) **Method:** Intramuscular injection

(b) **Dosage (daily):** 20 µg/Vial, 0.5 ml/Dose, for each dose of vaccination

(c) **Period:** Three dose intramuscular vaccination schedule (Day 0, Day 21 and Day 42)

4. Mode of clinical trial: Randomized, Double Blind, Placebo-Controlled Trial, Phase III Clinical Trial

5. Place where clinical trial is to be conducted: Mechi Zonal Hospital Bharatpur, Jhapa.

6. Of the person allowed conducting clinical trial:

(a) **Name, surname and address:** DR. KHEM BAHADUR KARKI (Principal Investigator)

(b) **Occupation:** DOCTOR

(c) **Qualifications:**

7. Validity period of license: TILL DATE, Sep 30, 2023

License receiver's:

Signature:

Date:

For
Date
2079/07/03

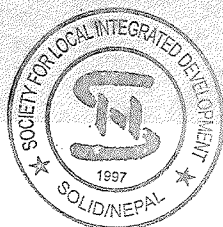
License issuing officer's

Signature:

Name: SHIWANI KHADGI

Date: October 20, 2022

Designation: SENIOR DRUG ADMIMISTRATOR



October 20, 2022

***NOTE**

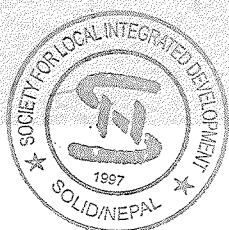
A. NAME OF THE CLINICAL TRIAL:

"A multicenter, randomized, double-blind, placebo-controlled, phase III trial to evaluate the efficacy, safety and immunogenicity of the Recombinant two-component COVID-19 Vaccine (CHO Cell) in adults aged 18 years and older"

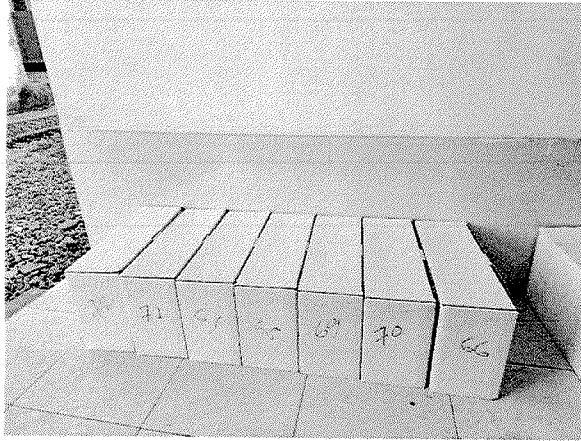
CONDITION APPLIED:

1. The clinical trial should be conducted as per approved protocol and Good Clinical Practices (GCP).
2. For any variation related to the protocol, application for amendment approval should be submitted to the Department.
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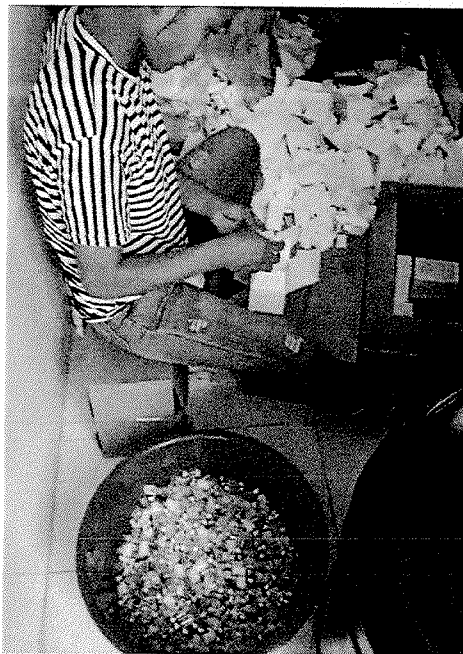
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Senior Drug Administration
10/10/2022
Government of Nepal
Ministry of Health and Population
Department of Drug Administration



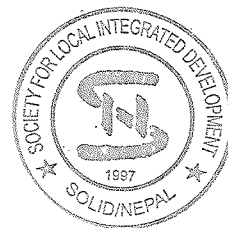
अनुसूची ४ - खोप धुलिकरण गर्दाको समयको फोटोहरू

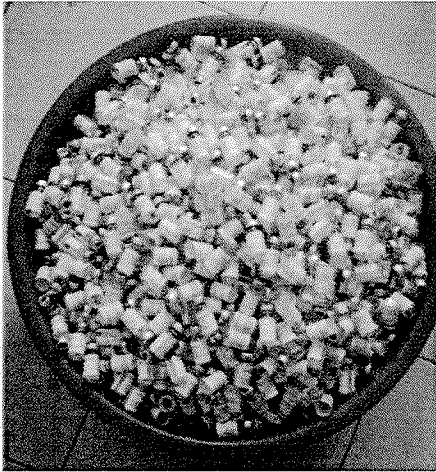


प्रयोग नगरिएका र गरिएका भ्याक्सिनका बट्टाहरूलाई भण्डारबाट बाहिर निकाली दहचोकमा लगियो



भ्याक्सिनको बट्टाको लेबल उपकाउँदै गरेको





प्रयोग गरिसकेको भ्याक्सिनका शिशीहरूलाई बट्टाबाट बाहिर निकाली सङ्कलन गरिएको



लेबल उप्काएपछि प्रयोग नगरिएको भ्याक्सिन गरिसकेको भ्याक्सिनका शिशीहरूलाई बट्टालाई प्लाष्टिकको ड्रममा राखेको ।



प्रयोग

प्लाष्टिकको ड्रममा राखेको

A global phase III clinical trial of the recombinant two component COVID-19 vaccine (CHO cells) in adults aged 18 years and above [Recov]



प्रयोग भएका र नभएका भ्याक्सिन शिशीहरूलाई छुट्टाछुट्टै ड्रममा राखि व्यास्थापन गर्ने तयारी गरिएको

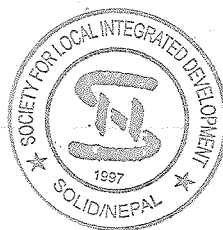


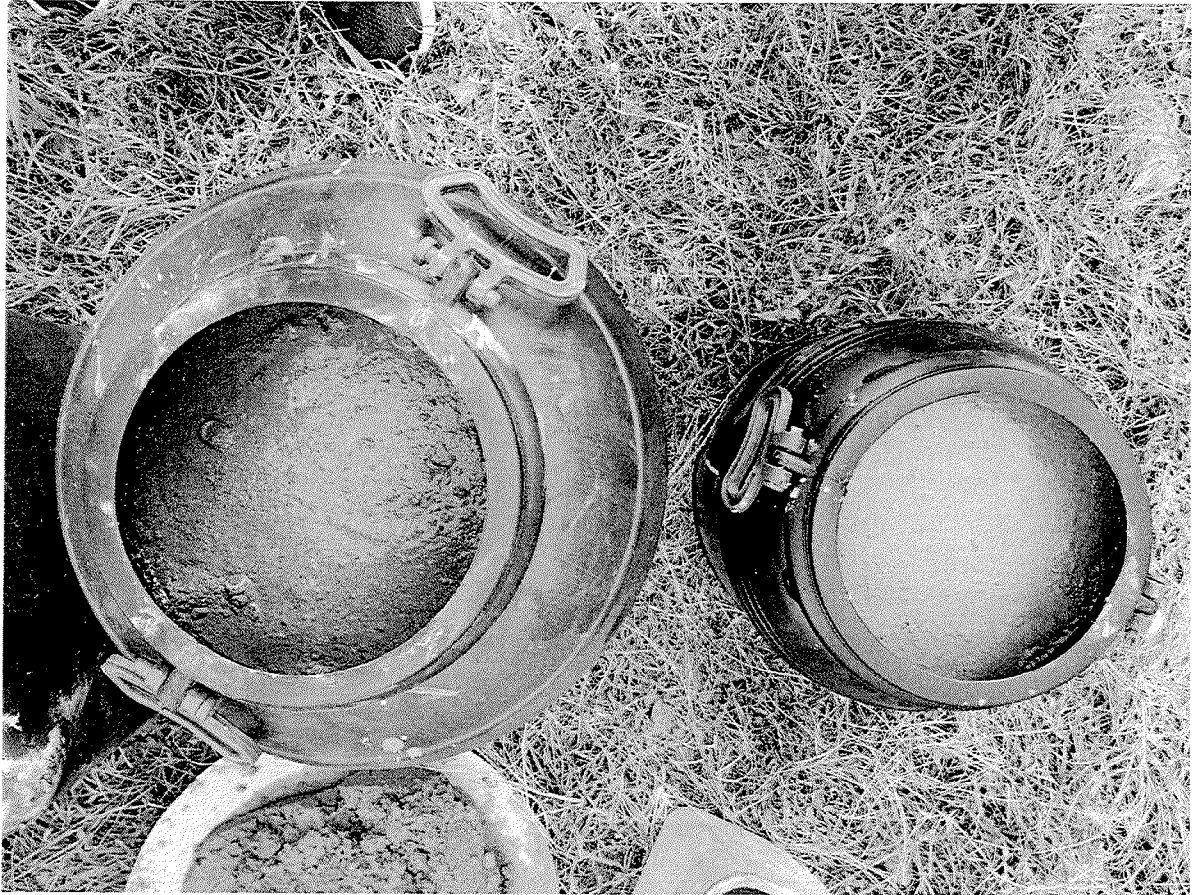
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प्रयोग भएका र नभएका भ्याक्सिन शिशीहरू रहेका
छुट्टाछुट्टै ड्रममा तीनभाग भ्याक्सिन शिशीहरू र एक
सिमेन्ट हुनेगरी भरिदै गरिएको

भाग

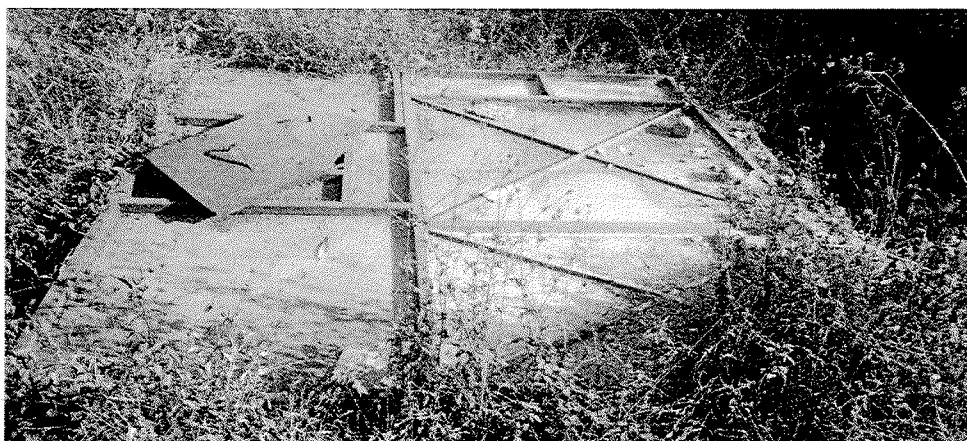




प्रयोग भएका र नभएका भ्याक्सिन शिशीहरू रहेका छुट्टाछुट्टै ड्रममा तीनभाग भ्याक्सिन शिशीहरू र एक भाग सिमेन्ट हुनेगरी भरिदै गरिएको



A global phase III clinical trial of the recombinant two component COVID-19 vaccine (CHO cells) in adults aged 18 years and above [Recov]



मनमोहन अस्पताल दहचोक, काठमाडौंमा कोभिड-१९ जन्य फोहर संकलन तथा विसर्जन गर्नका लागि बनाइएको सुरक्षित पिट

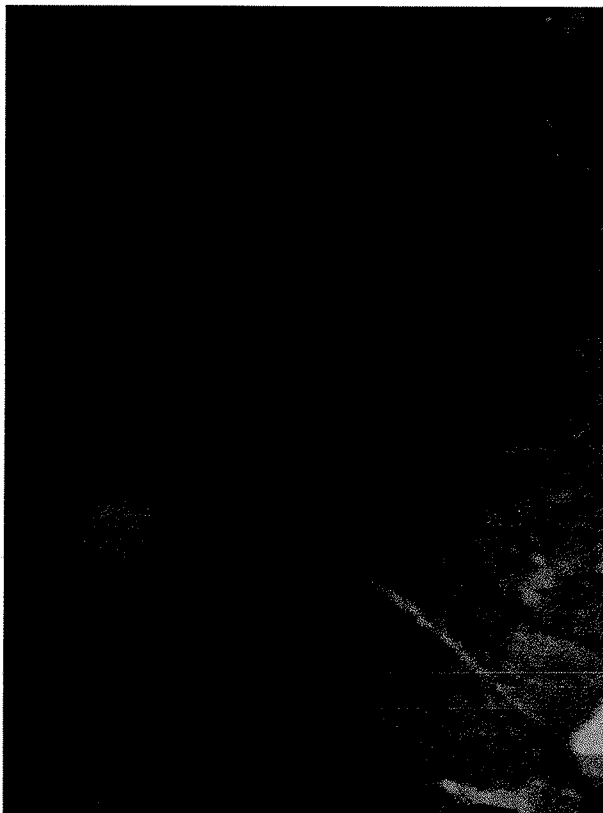


स्काभेटरको सहायताले खाडल खन्दै गरेको

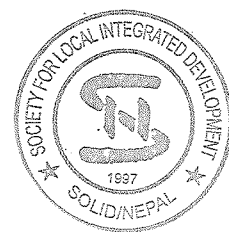


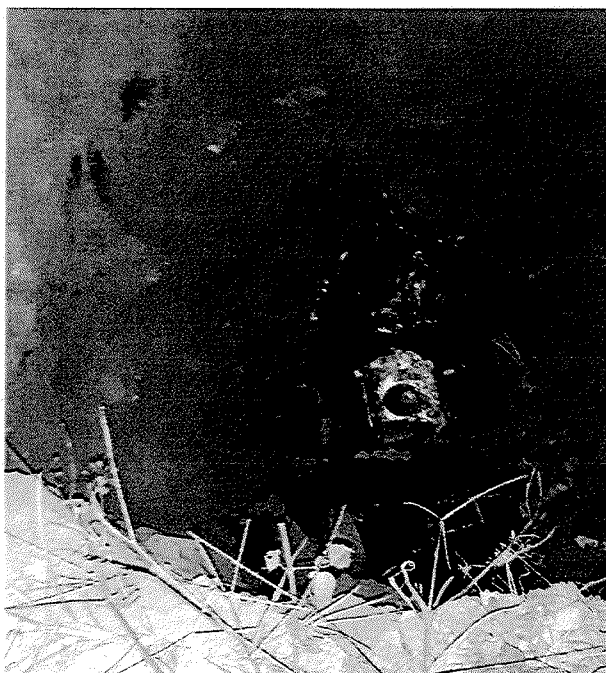


भ्याक्सिनका शिशीहरू भरिएको ड्रमलाई पुर्नका लागि तयार गरिएको खाडल



खाडलमा राखिएका ड्रमहरूलाई मिलाएर राखिदै गरेको





प्रयोग भएका र नभएका भ्याक्सिन शिशीहरूलाई छुट्टाछुट्टै ड्रममा तीन चौथाइ हुने गरी भरेर बाँकी एक चौथाई भागमा सिमेन्टले भरी खाडलमा पुर्नका लागि तयारी अवस्थामा राखिएको



भ्याक्सिनका शिशीहरू खाडलमा पुरेपछि



भ्याक्सिन बट्टाहरू, टाँस गरिएको लेबलहरूलाई सोही खाडलमाथि जलाइएको ।

Annex V

भरपाई

लिखितम बिपी कोइराला स्वास्थ्य विज्ञान प्रतिष्ठान धरान उपमहानगरपालिका, वडा नम्बर १८, धरान सुनसरीको तर्फबाट डा. सज्जिव कुमार शर्मा Site Investigator र स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल) का तर्फबाट Country PI डा खेम बहादुर कार्की बीच मिति २०७९।०६।२५ तदनुसार ११ अक्टोबर २०२२ मा चीनको RecBio Pharmaceuticals Company ले उत्पादन गरेको कोभिड-१९ विरुद्धको खोप CHO Cell को नेपालमा तेश्रो चरणको अनुसन्धान A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older परियोजना सञ्चालन गर्न MSR (Beijing) Pharmaceutical Consulting Co. Ltd. (CRO) सहितको त्रिपक्षिय सम्झौता भए अनुसार यस बिपी कोइराला स्वास्थ्य विज्ञान प्रतिष्ठान धरान, सुनसरीमा मिति २०७९।०८।०७ तदनुसार २५ नोभेम्बर २०२२ देखि मिति २०८०।०७।२९ तदनुसार १५ नोभेम्बर २०२३ सम्ममा अध्ययन खोपका सहभागीहरूको विवरण रहेको फाईल (Source Documents) २०८३ थान, सुसुचित सहमति पत्र (Informed Consent) रहेको फाईल २१०० थान, सहभागीहरूले खोप लगाइसकेपछिको दैनिक स्वास्थ्य अवस्थाको विवरण (Participant Diary) रहेको फाइलहरू २०९६ थान, खोपमा सहभागी हुन नसकेका (Screening Failure) व्यक्तिहरूको विवरणहरू रहेका २६८ थान फाइल सहितका विभिन्न कागजातहरू यसैसाथ संलग्न सूची (Check List) बमोजिम रजु गरी १६ वटा टीनका बाक्समा राखेर तालाबन्दी गरी सिलबन्दी समेत गरी अन्तिम सहभागीको अन्तिम भिजिटको ५ वर्षसम्म सुरक्षित राख्नका लागि प्रतिष्ठानले उपलब्ध गराएको सुरक्षित स्थलमा उल्लिखित कागजातहरू ICH-GCP द्वारा निर्धारण गरिएको प्रचलित मापदण्ड बमोजिम Investigator को निगरानीमा रहने र प्राकृतिक विपद् बाहेकका कुनैपनि कारणबाट उल्लिखित कागजपत्रहरू हराएमा, बिग्रिएमा वा नासिएमा प्रतिष्ठान पुर्णरूपमा जिम्मेवार रहनेछ भनी तपशिलका साक्षीहरूको रोहबरमा यो भरपाई गरिलियो दियो।

ईति सम्बत् २०८१ साल श्रावण २५ गते रोज ६ शुभम् ।

सामान बुझाउने

दायाँ

बायाँ

हस्ताक्षर -

नाम - डा. खेम बहादुर कार्की
Country PI, CHO-Cell, SOLID Nepal

सामान बुझिलिने

दायाँ

बायाँ

हस्ताक्षर -

नाम - डा. सज्जिव कुमार शर्मा
Site Investigator (Site 1001), CHO-Cell, BPKIHS

साक्षी

नाम

१. श्री ममित राई, BPKIHS, Dharan

२. श्री अजित आचार्य, SOLID Nepal

३. श्री अशेष प्याकुरेल, BPKIHS, Dharan

४. श्री सुवास कार्की, SOLID Nepal

हस्ताक्षर

दायाँ

बायाँ

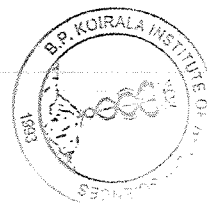


LIST OF BOX/TRUNK CONTENTS

Trunk	Description	Number of Files / Folders
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2	CHO Cell Vaccine Trial - Worksheet	234
3	CHO Cell Vaccine Trial - Worksheet	234
4	CHO Cell Vaccine Trial - Worksheet	234
5	CHO Cell Vaccine Trial - Worksheet	234
6	CHO Cell Vaccine Trial - Worksheet	234
7	CHO Cell Vaccine Trial - Worksheet	234
8	CHO Cell Vaccine Trial - Worksheet	234
9	CHO Cell Vaccine Trial - Worksheet	215
10	Diary Card	570
11	Diary Card	539
12	Diary Card	630
13	Diary Card	357
13	ICF	299
14	ICF	1039
15	Screening Failure ICF	32
15	Screening Failure Worksheet	185
16	ICF	762
16	Screening Failure ICF	51
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	Total Diary Card	2096
	Total ICF (of	2100
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	Total Screening Failure Worksheet (1 folder contains documents of multiple participants)	185 Folders



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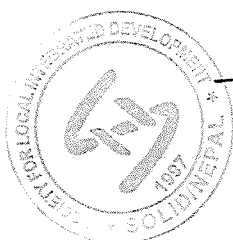
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CHO Cell Vaccine Trial - Worksheet						
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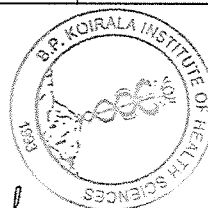


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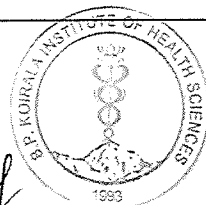
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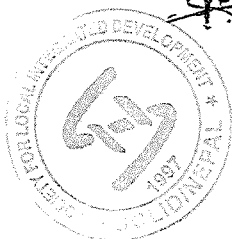
CHO Cell Vaccine Trial - Worksheet

Trunk no 2

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CHO Cell Vaccine Trial - Worksheet						
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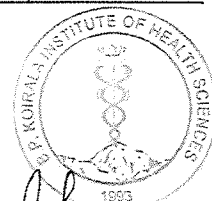
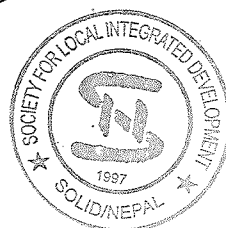


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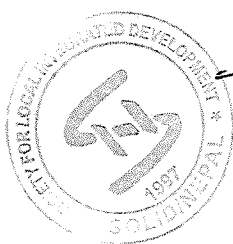


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CHO Cell Vaccine Trial - Worksheet

Trunk no 4

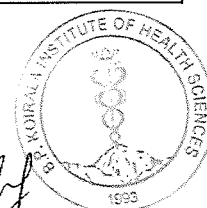
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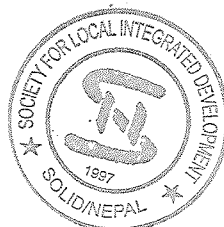
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CHO Cell Vaccine Trial - Worksheet						
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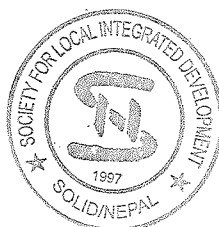
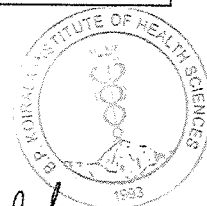
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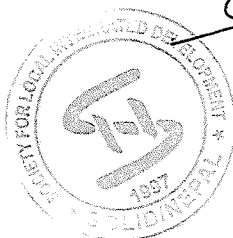
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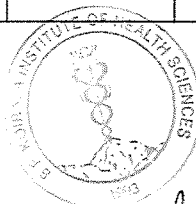


CHO Cell Vaccine Trial - Worksheet						
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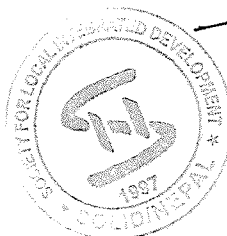


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CHO Cell Vaccine Trial - Worksheet						
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CHO Cell Vaccine Trial - Worksheet

Trunk no 8

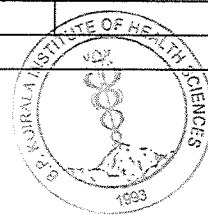
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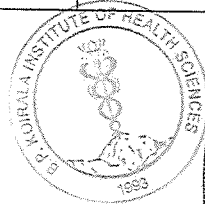


CHO Cell Vaccine Trial - Worksheet

Trunk no 9

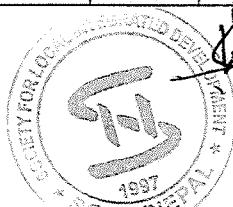
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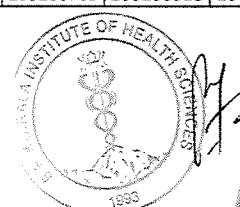
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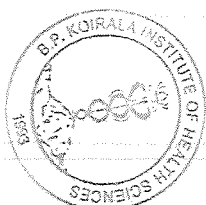
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Trunk no 15 - Screening faliure Worksheet & ICF

Screening Failure Worksheet - ALL

& Screening Failure ICF - 32 Folders

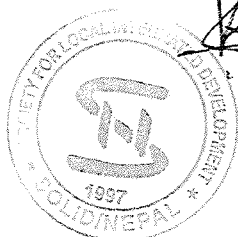


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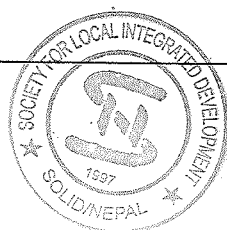
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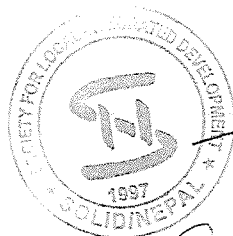
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CONTENTS OF SOURCE DOCUMENT-FOLDER

- V1- Worksheet
- V2- Worksheet
- V3- Worksheet
- V4- Worksheet
- V5- worksheet (Immunogenicity only)
- V6- worksheet
- V7 – worksheet
- V8 – Work sheet
- V9 – Worksheet
- Participant File binder list
- Participant Identity form
- ICF re consent form
- RT-PCR test report
- Rapid Antibody test report
- UPT test (Only female)
- IP dispensing log
- Randomization number slip
- KIT dispense log -1
- IP dispense log- 1
- ID dispation, collection and preparation form -1
- IP Administration form
- UPT test report
- Kit dispense log –2 dose
- IP dispense log – 2 dose
- IP administration form 2 dose
- UPT test report V3
- Kit dispense log- 3 dose
- IP dispense log- 3 dose
- IP Administration form 3 dose
- AE log
- Source Document Review Form
- Completion/End of study form
- Sample Requisition Form (Immunogenicity only)

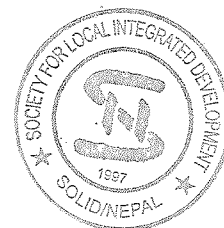
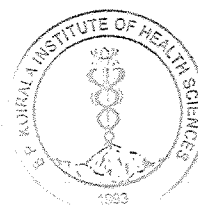


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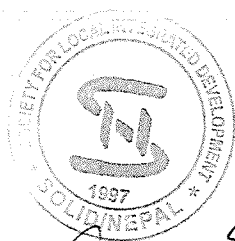
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CONTENTS OF ICF FOLDERS

1. Sign ICF V1.0
2. Identity of Participants (Copy of Citizenship)
3. Authorization for filling Diary Card
4. Sign ICF V2.1



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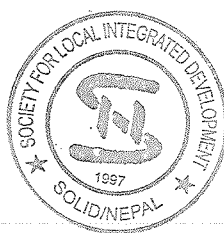
CONTENTS OF DAIRY CARD FOLDERS

Immunogenicity

- V1&V2 solicited and unsolicited diary card
- V3 solicited and unsolicited diary card
- V4 solicited and unsolicited diary card
- V5 unsolicited diary card

Safety

- V1&V2 solicited and unsolicited diary card
- V3 solicited and unsolicited diary card
- V4 solicited and unsolicited diary card



भरपाई

लिखित तत्कालिन मेची अञ्चल अस्पताल हाल प्रादेशिक अस्पताल भद्रपुर, भद्रपुर-८, झापाको तर्फबाट तत्कालिन अस्पतालका Chief Medical Superintendent डा. टंक प्रसाद बराकोटी, Site Investigator डा. मनिष सुवेदी Site Co-Investigator र स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल)का तर्फबाट Country PI डा खेम बहादुर कार्की बीच मिति २०७९।०६।२४ तदनुसार १० अक्टोबर २०२२ मा चीनको RecBio Pharmaceuticals Company ले उत्पादन गरेको कोभिड-१९ विरुद्धको खोप CHO Cell को नेपालमा तेश्रो चरणको अनुसन्धान A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older परियोजना सञ्चालन गर्न MSR (Beijing) Pharmaceutical Consulting Co. Ltd. (CRO) सहितको त्रिपक्षिय सम्झौता भए अनुसार यस प्रादेशिक अस्पताल भद्रपुर, भद्रपुर-८, झापामा मिति २०७९।०८।२६ तदनुसार १२ डिसेम्बर २०२२ देखि मिति २०८०।०७।२३ तदनुसार ९ नोभेम्बर २०२३ सम्ममा अध्ययन खोपका सहभागीहरूको विवरण रहेको फाईल (Source Documents) १५०५ थान, सुसुचित सहमति पत्र (Inform Consent) रहेको फाईल १५०५ थान, खोपमा सहभागी हुन नसकेका (Screening Failure) व्यक्तिहरूको विवरण रहेको १३८ थान फाइल, अन्य विवरणहरू रहेका ६० थान फाइलका विभिन्न कागजातहरू यसैसाथ संलग्न सूची (Check List) बमोजिम रुजु गरी ११ वटा टीनका बाकसमा राखेर तालाबन्दी गरी सिलबन्दी समेत गरी अन्तिम सहभागीको अन्तिम भिजिटको ५ वर्षसम्म सुरक्षित राख्नका लागि अस्पतालले उपलब्ध गराएको आफ्नै भवनमा उल्लिखित कागजातहरू ICH-GCP द्वारा निर्धारण गरिएको प्रचलित मापदण्ड बमोजिम Investigator को निगरानीमा रहने र प्राकृतिक विपद् बाहेकका कुनैपनि कारणबाट उल्लिखित कागजपत्रहरू हराएमा, बिग्रेमा वा नासिएमा अस्पताल पुर्णरूपमा जिम्मेवार रहनेछ भनी तपशिलका साक्षीहरूको रोहबरमा यो भरपाई गरिलियो दियो।

ईति सम्बत् २०८१ साल श्रावण १० गते रोज ५ शुभम् ।

सामान बुझाउने

दायाँ

बायाँ

नाम — अजित आचार्य

Project Coordinator, SOLID Nepal

हस्ताक्षर -



सामान बुझिलिने

दायाँ

बायाँ

नाम — डा. मनिष सुवेदी

Site Co-Investigator (Site 1002)

हस्ताक्षर -



साक्षी

नाम

१. डा. टंक प्रसाद बराकोटी, Site Investigator (Site 1002)

२. डा. खेम बहादुर कार्की, Country PI, SOLID NEPAL

३. श्री मनोज कुमार पोखेल, Provincial Hospital Bhadrapur

४. श्री सुवास कार्की, SOLID Nepal



List of Box Contents

Box	Source Documents	Total
Box 1	100200001 to 100200322	218
Box 2	100200323 to 100200605	213
Box 3	100200606 To 100200880	216
Box 4	100200882 to 100201176	224
Box 5	100201175 To 100201501	228
Box 6	100201502 To 100201774	217
Box 7	1002075 To 100201988	189
Box 8	ICF 100200001 To100200964	714
Box 9	ICF 100200965 To100201858	678
Box 10	ICF 100201859 To 100201988	127
	Others file 15 File/Folders	
Box 11	Others related File/ Folders	45



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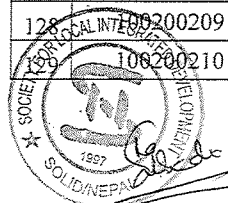
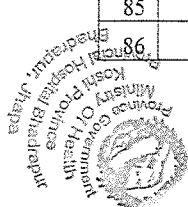
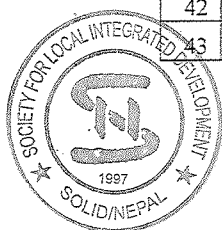


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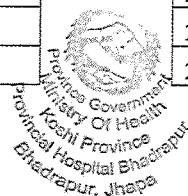
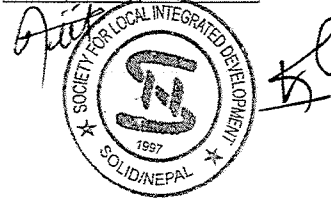


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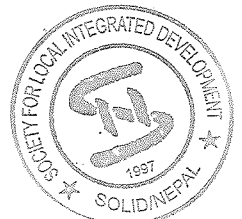
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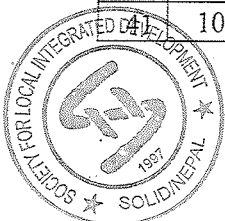


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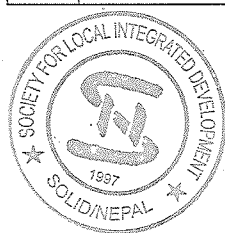


Box Number 2
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Province Government
Ministry Of Health
Koshi Province
Provincial Hospital Bhadrapur
Bhadrapur, Jhapa

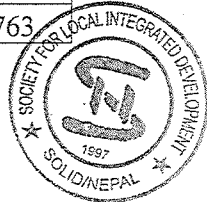
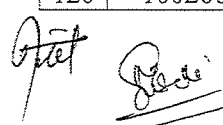
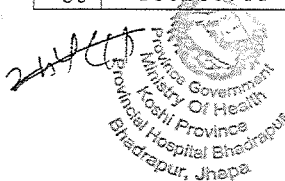
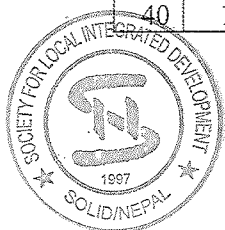


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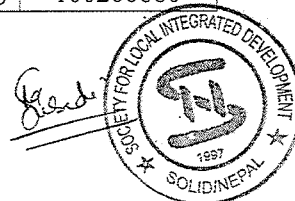
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SN	Screening No.
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154	100200802
155	100200803
156	100200804
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160	100200808
161	100200809
162	100200810
163	100200811
164	100200812
165	100200813
166	100200814
167	100200815
168	100200816
169	100200817
170	100200818
171	100200819
172	100200821
173	100200822
174	100200824
175	100200828
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178	100200831
179	100200832
180	100200833
181	100200834
182	100200837
183	100200840
184	100200841

SN	Screening No.
185	100200842
186	100200845
187	100200846
188	100200847
189	100200849
190	100200850
191	100200851
192	100200852
193	100200853
194	100200854
195	100200855
196	100200856
197	100200858
198	100200859
199	100200860
200	100200863
201	100200864
202	100200865
203	100200866
204	100200867
205	100200868
206	100200870
207	100200871
208	100200872
209	100200873
210	100200874
211	100200875
212	100200876
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216	100200880




 Province Government
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 Koshi Province
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 Bhadrapur, Jhapa

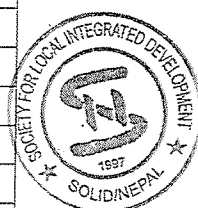
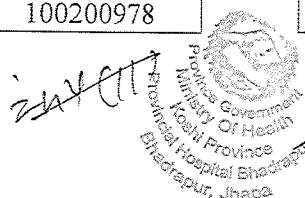


Box Number 4
Source Document File List (CHO Cell) Site 1002

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6	100200887
7	100200889
8	100200890
9	100200891
10	100200892
11	100200893
12	100200896
13	100200897
14	100200898
15	100200899
16	100200900
17	100200901
18	100200902
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32	100200924
33	100200926
34	100200927
35	100200928
36	100200929
37	100200930
38	100200931
39	100200932

SN	Screening No.
40	100200933
41	100200935
42	100200936
43	100200937
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75	100200974
76	100200975
77	100200976
78	100200978

SN	Screening No.
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83	100200984
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85	100200986
86	100200994
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88	100200997
89	100201000
90	100201001
91	100201003
92	100201004
93	100201008
94	100201010
95	100201011
96	100201012
97	100201013
98	100201014
99	100201015
100	100201016
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103	100201022
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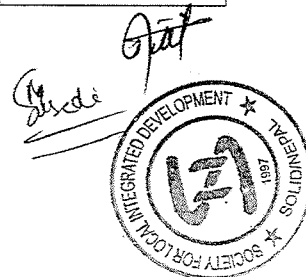
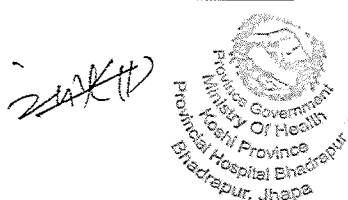


Box Number 4
Source Document File List (CHO Cell) Site 1002

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125	100201049
126	100201050
127	100201051
128	100201053
129	100201054
130	100201055
131	100201056
132	100201057
133	100201058
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146	100201071
147	100201072
148	100201074
149	100201075
150	100201078
151	100201079
152	100201081
153	100201082

SN	Screening No.
154	100201083
155	100201085
156	100201086
157	100201087
158	100201088
159	100201089
160	100201091
161	100201092
162	100201093
163	100201095
164	100201097
165	100201098
166	100201099
167	100201100
168	100201101
169	100201105
170	100201106
171	100201107
172	100201112
173	100201113
174	100201114
175	100201117
176	100201118
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182	100201129
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187	100201135
188	100201136
189	100201137

SN	Screening No.
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191	100201138
192	100201139
193	100201139
194	100201140
195	100201141
196	100201143
197	100201144
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214	100201163
215	100201164
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224	100201176

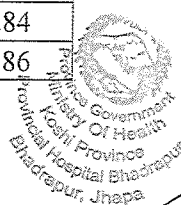
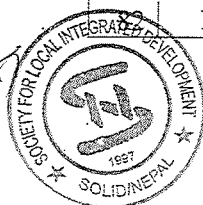


Box Number 5
Source Document File List (CHO Cell) Site 1002

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12	100201194
13	100201197
14	100201198
15	100201199
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24	100201209
25	100201210
26	100201211
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29	100201216
30	100201217
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32	100201220
33	100201221
34	100201222
35	100201223
36	100201224
37	100201225
38	100201226
39	100201227
40	100201228
41	100201229

SN	Screening No.
42	100201230
43	100201231
44	100201232
45	100201233
46	100201236
47	100201239
48	100201240
49	100201241
50	100201242
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73	100201272
74	100201273
75	100201274
76	100201276
77	100201277
78	100201278
79	100201280
80	100201281
81	100201284
	100201286

SN	Screening No.
83	100201287
84	100201288
85	100201289
86	100201291
87	100201293
88	100201294
89	100201295
90	100201297
91	100201298
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114	100201325
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120	100201332
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123	100201340



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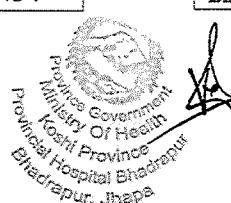
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Source Document File List (CHO Cell) Site 1002

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135	100201358
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137	100201360
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150	100201382
151	100201384
152	100201385
153	100201387
154	100201388
155	100201389
156	100201390
157	100201393
158	100201394

SN	Screening No.
159	100201395
160	100201397
161	100201398
162	100201399
163	100201405
164	100201407
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166	100201417
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172	100201424
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181	100201434
182	100201437
183	100201439
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185	100201441
186	100201443
187	100201446
188	100201448
189	100201449
190	100201451
191	100201452
192	100201453
193	100201454

SN	Screening No.
194	100201455
195	100201456
196	100201457
197	100201458
198	100201459
199	100201460
200	100201461
201	100201462
202	100201463
203	100201467
204	100201468
205	100201469
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207	100201472
208	100201475
209	100201477
210	100201480
211	100201481
212	100201482
213	100201483
214	100201484
215	100201487
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218	100201490
219	100201491
220	100201492
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225	100201498
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228	100201501

24/11/17



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Box Number 6
Source Document File List (CHO Cell) Site 1002

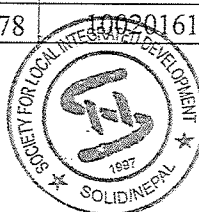
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10	100201523
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14	100201529
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16	100201531
17	100201532
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19	100201536
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35	100201554
36	100201555
37	100201556
38	100201557
39	100201558

SN	Screening No.
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41	100201560
42	100201561
43	100201562
44	100201563
45	100201564
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47	100201566
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69	100201597
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71	100201601
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73	100201608
74	100201609
75	100201610
76	100201611
77	100201613
78	100201614

SN	Screening No.
79	100201615
80	100201616
81	100201619
82	100201620
83	100201621
84	100201622
85	100201623
86	100201624
87	100201628
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110	100201651
111	100201652
112	100201653
113	100201654
114	100201655
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116	100201659
117	100201660



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Provincial Hospital Bhadrapur, Jhapa

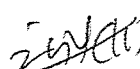
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Box Number 6
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147	100201695
148	100201696
149	100201697
150	100201698
151	100201699

SN	Screening No.
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155	100201704
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157	100201706
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159	100201708
160	100201709
161	100201710
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163	100201712
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165	100201714
166	100201715
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174	100201725
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179	100201731
180	100201732
181	100201733
182	100201734
183	100201735
184	100201736
185	100201737

SN	Screening No.
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187	100201739
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208	100201763
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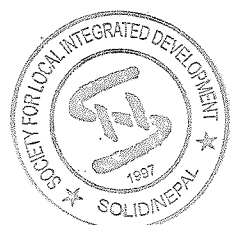


Box Number 7
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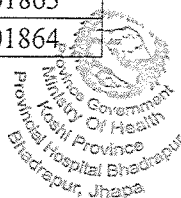
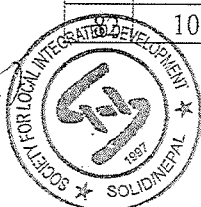
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37	100201815
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39	100201817
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41	100201819

SN	Screening No.
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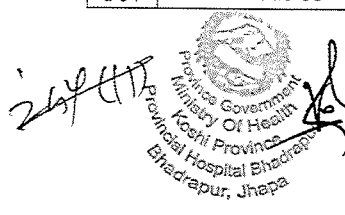
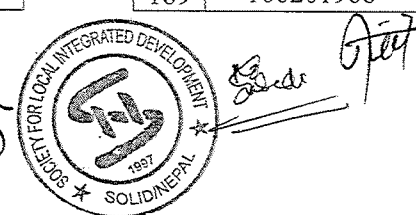
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Box Number 7
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145	100201936

SN	Screening No.
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166	100201962
167	100201963

SN	Screening No.
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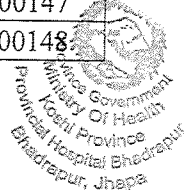
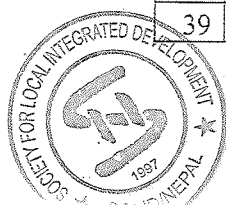


Box Number 8
ICF File List (CHO Cell) Site 1002

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35	100200083
36	100200085
37	100200086
38	100200090
39	100200091

SN	Screening No.
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47	100200101
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67	100200124
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76	100200139
77	100200147
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SN	Screening No.
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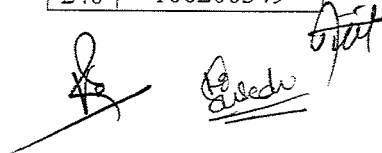
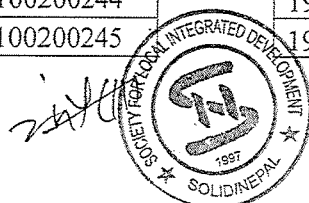
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Box Number 8
ICF File List (CHO Cell) Site 1002

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156	100200243
157	100200244
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SN	Screening No.
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161	100200249
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164	100200254
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194	100200294
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196	100200297
197	100200298
198	100200299
199	100200300

SN	Screening No.
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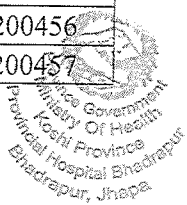
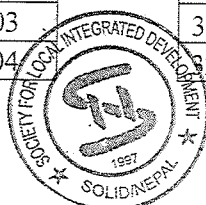


Box Number 8
ICF File List (CHO Cell) Site 1002

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251	100200361
252	100200362
253	100200363
254	100200364
255	100200365
256	100200366
257	100200367
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259	100200369
260	100200370
261	100200373
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275	100200396
276	100200397
277	100200400
278	100200401
279	100200402
280	100200403
281	100200404

SN	Screening No.
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283	100200406
284	100200407
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287	100200413
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320	100200455
321	100200456
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SN	Screening No.
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331	100200467
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336	100200473
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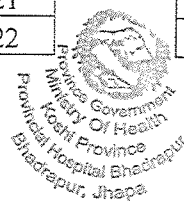
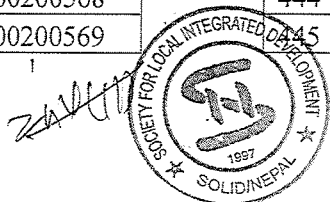
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Box Number 8
ICF File List (CHO Cell) Site 1002

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397	100200560
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399	100200562
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401	100200565
402	100200567
403	100200568
404	100200569

SN	Screening No.
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411	100200577
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416	100200582
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421	100200590
422	100200592
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424	100200594
425	100200595
426	100200596
427	100200599
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438	100200612
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SN	Screening No.
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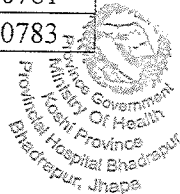
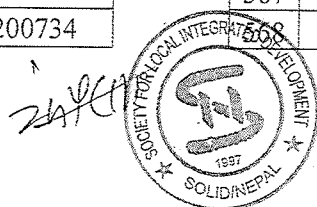
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Box Number 8
ICF File List (CHO Cell) Site 1002

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520	100200723
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523	100200727
524	100200728
525	100200729
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SN	Screening No.
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551	100200762
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557	100200769
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560	100200772
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566	100200779
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568	100200783

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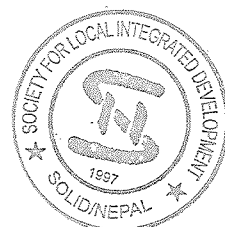
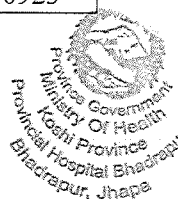
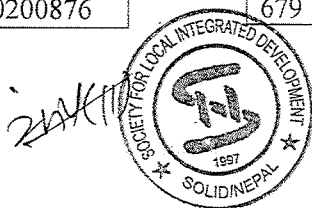
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Box Number 8
ICF File List (CHO Cell) Site 1002

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619	100200846
620	100200847
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622	100200850
623	100200851
624	100200852
625	100200853
626	100200854
627	100200855
628	100200856
629	100200858
630	100200859
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632	100200863
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634	100200865
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636	100200867
637	100200868
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644	100200876

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SN	Screening No.
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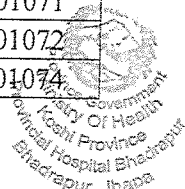


Box Number 9
ICF File List (CHO Cell) Site 1002

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SN	Screening No.
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81	100201072
82	100201074

SN	Screening No.
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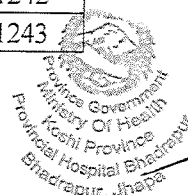
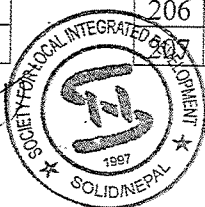
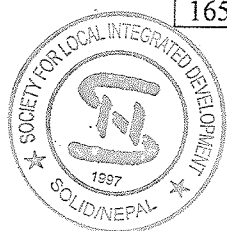
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Box Number 9
ICF File List (CHO Cell) Site 1002

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SN	Screening No.
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198	100201230
199	100201231
200	100201232
201	100201233
202	100201236
203	100201239
204	100201240
205	100201241
206	100201242
207	100201243

SN	Screening No.
208	100201244
209	100201245
210	100201247
211	100201248
212	100201249
213	100201250
214	100201251
215	100201252
216	100201253
217	100201254
218	100201256
219	100201257
220	100201258
221	100201259
222	100201261
223	100201262
224	100201263
225	100201265
226	100201269
227	100201270
228	100201271
229	100201272
230	100201273
231	100201274
232	100201276
233	100201277
234	100201278
235	100201280
236	100201281
237	100201284
238	100201286
239	100201287
240	100201288
241	100201289
242	100201291
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244	100201294
245	100201295
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247	100201298
248	100201300
249	100201301



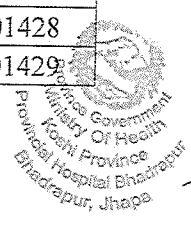
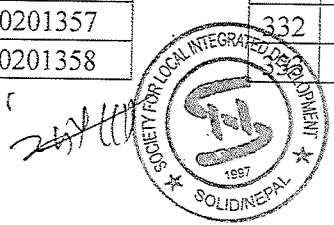
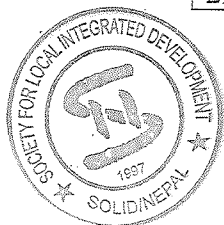
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Box Number 9
ICF File List (CHO Cell) Site 1002

SN	Screening No.
250	100201302
251	100201303
252	100201304
253	100201306
254	100201307
255	100201308
256	100201309
257	100201310
258	100201311
259	100201312
260	100201314
261	100201316
262	100201317
263	100201318
264	100201319
265	100201320
266	100201321
267	100201322
268	100201323
269	100201324
270	100201325
271	100201326
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274	100201330
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276	100201332
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279	100201340
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281	100201343
282	100201344
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284	100201347
285	100201349
286	100201351
287	100201352
288	100201355
289	100201356
290	100201357
291	100201358

SN	Screening No.
292	100201359
293	100201360
294	100201362
295	100201363
296	100201365
297	100201366
298	100201367
299	100201368
300	100201372
301	100201374
302	100201376
303	100201377
304	100201379
305	100201381
306	100201382
307	100201384
308	100201385
309	100201387
310	100201388
311	100201389
312	100201390
313	100201393
314	100201394
315	100201395
316	100201397
317	100201398
318	100201399
319	100201405
320	100201407
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324	100201419
325	100201420
326	100201422
327	100201423
328	100201424
329	100201425
330	100201426
331	100201427
332	100201428
	100201429

SN	Screening No.
334	100201430
335	100201432
336	100201433
337	100201434
338	100201437
339	100201439
340	100201440
341	100201441
342	100201443
343	100201446
344	100201448
345	100201449
346	100201451
347	100201452
348	100201453
349	100201454
350	100201455
351	100201456
352	100201457
353	100201458
354	100201459
355	100201460
356	100201461
357	100201462
358	100201463
359	100201467
360	100201468
361	100201469
362	100201470
363	100201472
364	100201475
365	100201477
366	100201480
367	100201481
368	100201482
369	100201483
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371	100201487
372	100201488
373	100201489
374	100201490
375	100201491



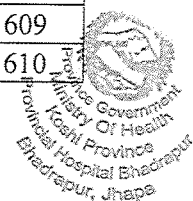
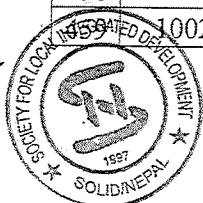
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Box Number 9
ICF File List (CHO Cell) Site 1002

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379	100201495
380	100201496
381	100201498
382	100201499
383	100201500
384	100201501
385	100201502
386	100201503
387	100201507
388	100201508
389	100201509
390	100201510
391	100201511
392	100201512
393	100201516
394	100201523
395	100201524
396	100201525
397	100201528
398	100201529
399	100201530
400	100201531
401	100201532
402	100201535
403	100201536
404	100201537
405	100201538
406	100201539
407	100201542
408	100201543
409	100201544
410	100201545
411	100201546
412	100201547
413	100201548
414	100201549
415	100201550
416	100201551
417	100201552

SN	Screening No.
418	100201553
419	100201554
420	100201555
421	100201556
422	100201557
423	100201558
424	100201559
425	100201560
426	100201561
427	100201562
428	100201563
429	100201564
430	100201565
431	100201566
432	100201567
433	100201568
434	100201569
435	100201570
436	100201572
437	100201574
438	100201577
439	100201578
440	100201579
441	100201580
442	100201581
443	100201584
444	100201586
445	100201587
446	100201588
447	100201590
448	100201591
449	100201592
450	100201594
451	100201595
452	100201596
453	100201597
454	100201598
455	100201601
456	100201603
457	100201608
458	100201609
459	100201610

SN	Screening No.
460	100201611
461	100201613
462	100201614
463	100201615
464	100201616
465	100201619
466	100201620
467	100201621
468	100201622
469	100201623
470	100201624
471	100201628
472	100201625
473	100201626
474	100201627
475	100201629
476	100201630
477	100201631
478	100201632
479	100201633
480	100201634
481	100201635
482	100201636
483	100201637
484	100201639
485	100201641
486	100201642
487	100201643
488	100201644
489	100201645
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492	100201649
493	100201650
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501	100201660



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Box Number 9
ICF File List (CHO Cell) Site 1002

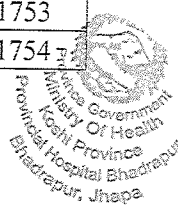
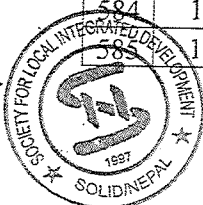
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506	100201665
507	100201666
508	100201668
509	100201669
510	100201672
511	100201673
512	100201674
513	100201675
514	100201676
515	100201677
516	100201678
517	100201679
518	100201681
519	100201682
520	100201683
521	100201684
522	100201685
523	100201686
524	100201687
525	100201688
526	100201689
527	100201691
528	100201692
529	100201693
530	100201694
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533	100201697
534	100201698
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536	100201701
537	100201702
538	100201703
539	100201704
540	100201705
541	100201706
542	100201707
543	100201708

SN	Screening No.
544	100201709
545	100201710
546	100201711
547	100201712
548	100201713
549	100201714
550	100201715
551	100201716
552	100201717
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557	100201722
558	100201725
559	100201726
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561	100201728
562	100201729
563	100201731
564	100201732
565	100201733
566	100201734
567	100201735
568	100201736
569	100201737
570	100201738
571	100201739
572	100201740
573	100201741
574	100201742
575	100201743
576	100201744
577	100201745
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579	100201747
580	100201748
581	100201749
582	100201751
583	100201752
584	100201753
585	100201754

SN	Screening No.
586	100201755
587	100201756
588	100201757
589	100201758
590	100201760
591	100201761
592	100201763
593	100201764
594	100201766
595	100201767
596	100201769
597	100201770
598	100201771
599	100201772
600	100201773
601	100201774
602	100201775
603	100201777
604	100201778
605	100201779
606	100201780
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608	100201782
609	100201783
610	100201784
611	100201785
612	100201786
613	100201787
614	100201788
615	100201789
616	100201790
617	100201791
618	100201792
619	100201793
620	100201794
621	100201795
622	100201796
623	100201797
624	100201798
625	100201799
626	100201800
627	100201801



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Box Number 9
ICF File List (CHO Cell) Site 1002

SN	Screening No.
628	100201802
629	100201804
630	100201805
631	100201806
632	100201807
633	100201808
634	100201809
635	100201811
636	100201812
637	100201814
638	100201815
639	100201816
640	100201817
641	100201818
642	100201819
643	100201820
644	100201821

SN	Screening No.
645	100201822
646	100201823
647	100201824
648	100201825
649	100201826
650	100201827
651	100201828
652	100201829
653	100201830
654	100201831
655	100201832
656	100201833
657	100201834
658	100201835
659	100201836
660	100201837
661	100201838

SN	Screening No.
662	100201839
663	100201841
664	100201842
665	100201844
666	100201845
667	100201846
668	100201847
669	100201848
670	100201849
671	100201850
672	100201852
673	100201853
674	100201854
675	100201855
676	100201856
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678	100201858

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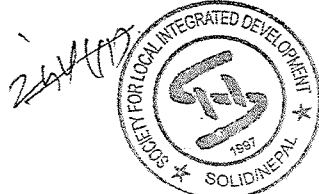


Box Number 10
ICF, Screening Failure ICF and Worksheet File List (CHO Cell) Site 1002

SN	Screening No.
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3	100201861
4	100201863
5	100201864
6	100201865
7	100201866
8	100201867
9	100201868
10	100201870
11	100201871
12	100201872
13	100201873
14	100201874
15	100201875
16	100201876
17	100201877
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19	100201879
20	100201880
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22	100201882
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24	100201884
25	100201885
26	100201886
27	100201887
28	100201890
29	100201891
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31	100201896
32	100201897
33	100201898
34	100201899
35	100201900
36	100201901
37	100201902
38	100201904

SN	Screening No.
39	100201905
40	100201906
41	100201907
42	100201908
43	100201909
44	100201910
45	100201911
46	100201912
47	100201913
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69	100201937
70	100201938
71	100201940
72	100201941
73	100201943
74	100201944
75	100201945
76	100201947

SN	Screening No.
77	100201949
78	100201950
79	100201951
80	100201952
81	100201953
82	100201954
83	100201956
84	100201957
85	100201958
86	100201959
87	100201960
88	100201961
89	100201962
90	100201963
91	100201964
92	100201965
93	100201968
94	100201970
95	100201971
96	100201972
97	100201973
98	100201974
99	100201975
100	100201976
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102	100201978
103	100201979
104	100201980
105	100201981
106	100201982
107	100201983
108	100201984
109	100201985
110	100201986
111	100201987
112	100201988



Box Number 10
ICF, Screening Failure ICF and Worksheet File List (CHO Cell) Site 1002

- 113. Screening Failure ICF – 68 Folders
- 114. Screening Failure Worksheet – 70 Folders
- 115. Participant visit register – 2 books
- 116. Record form of Participant leaving form- 3 folders
- 117. ICF left by Participants – 2 folders
- 118. Lab temperature log – 1 folder
- 119. Material Requisition form – 1 Folder
- 120. IP Inventory log I, II,III,IV – 4 Folders
- 121. IP Transport Form – 1 Folder
- 122. Observation timing Checklist 1st, 2nd, 3rd dose – 3 Folders
- 123. PCR Specification Identification form – 1 My Clear Bag
- 124. SAE/AESI/Pregnancy Quarry form – 1 My Clear Bag
- 125. Participant Screening and Enrollment log- 1 My clear Bag
- 126. SAE report form – 1 My Clear Bag
- 127. Witness Tracker form – 1 My Clear Bag

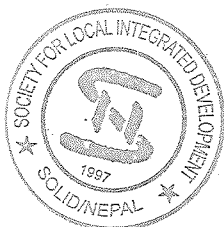


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Box Number 11
Source Document related File List (CHO Cell) Site 1002

List of folders

1. Participant Observation Register (30 Minutes) - 5 Registers
2. Vaccination register – 2 Register
3. Participant Identification Code list - 1 Folder
4. Inform Consent Registration – 1 Folder
5. Participant Screening and enrollment log V9 – 1 Folder
6. Participant Screening and enrollment log V8 – 1 Folder
7. AE Log- 1 Folder
8. Visit 7 participant enrollment log - 1 folder
9. Participant enrollment log 1st dose – 2 Folders
10. Participant enrollment log 2nd dose – 2 Folders
11. Participant enrollment log 3rd dose – 2 Folders
12. Witness Contact Log – 3 Folders
13. AE and CM Log V2.0 – 1 My Clear Bag
14. Study Completion form – 1 My Clear Bag
15. SAE and Pregnancy Medical record – 1 Yellow Bag
16. Medical records of Participants - 1 Bundle Files
17. Participant Medical record and invoices – 3 My Clear Bags
18. Site PCR Identification form V1, V2, V3 and V4 - 5 My Clear Bags
19. Unscheduled Visit (Visit 9) - 1 My Clear Bag
20. Sample Requisition form 16.2.1 – 2 my Clear Bags
21. NHRC and DDA Submission letters – 4 My Clear Bags
22. ISF Study forms log template – 3 My Clear bags
23. F8.1 CRF Sample V1.0 and V3.0 – 1 My Clear Bag
24. F4.1 Protocol V1, V2 and V3 - 1 My Clear Bag
25. Study Guidelines and Manual – 3 My Clear Bag
26. Contact Report (F 13.3.1) – 1 My Clear bag
27. F11.7 – 1 My Clear Bag
28. Investigator Brochure (V1.3, 1.4 and v2.0) – 1 My Clear Bag
29. Investigator Brochure – 1 Book
30. 20 jan PCR record – 2 My Clear Bags
31. 16.2.1 Sample requisition form – 1 My Clear Bag
32. RT PCR report – 1 My Clear Bag
33. F12.4 Hiro Kit Order form – 1 My clear Bag
34. IP Transfer temperatures log (Central to Site) - 1 My Clear bag
35. F 16.2.2 Sample Transfer record – 1 My Clear Bag
36. F12.6 Site IP Inventory unused vaccine record – 1 My Clear Bag
37. F13.3.1 Contact report – 2 My Clear Bags
38. Monitoring Visit report for IP – 3 My Clear Bag
39. RT PCR Report – 6 My Clear Bags
40. Equipment Deliver Sheet SOLID to MSR – 1 My Clear Bag
41. Withdrawal ICF List - 1 Folder
42. ICF left by Participant – 1 Folder
43. Mock Drill Report - 1 Folder
44. AE Log – 1 My Clear bag
45. Concomitant Medication log – 1 My Clear bag



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Contents of Source Documents

1. V1- Worksheet
2. V2- Worksheet
3. V3- Worksheet
4. V6- worksheet
5. V7 – worksheet
6. V8 – Work sheet
7. V9 – Worksheet
8. Participant File binder list
9. Participant Identity form
10. ICF recon sent form
11. RT-PCR test report
12. Rapid Antibody test report
13. UPT test (Only female)
14. IP dispensing log
15. Randomization number slip
16. KIT dispense log -1
17. IP dispense log- 1
18. ID dispassion, collection and preparation form -1
19. IP Administration form
20. Participant diary V3 (Solicited)
21. Participant Diary V3 (Un solicited)
22. UPT test report
23. Kit dispense log –2 dose
24. IP dispense log – 2 dose
25. IP administration form 2 dose
26. Participant diary (Solicited V2)
27. Participant diary (Unsolicited V2)
28. UPT test report V3
29. Kit dispense log- 3 dose
30. IP dispense log- 3 dose
31. IP Administration form 3 dose
32. Participant diary (Solicited V4)
33. Participant diary (Unsolicited V4)
34. AE log
35. Source Document Review Form
36. Completion/End of study form



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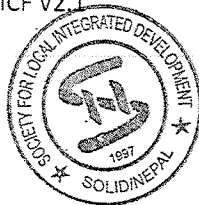
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Contents of ICF Folders

1. Sign ICF V1.0
2. Identity of Participants (Copy of Citizenship)
3. Authorization for filling Diary Card
4. Sign ICF V2.1



भरपाई

लिखितम नेपाल स्वास्थ्य सेवा सहकारी संस्था लिमिटेड (NEHCO)ले सञ्चालन गरेको मनमोहन मेमोरिएल मेडिकल कलेज तथा शिक्षण अस्पताल (MMMCTH), का. म. न. पा. १५, स्वयम्भु काठमाडौंको तर्फबाट प्रमुख कार्यकारी निर्देशक डा. नास्तु शर्मा र डा. केदार प्रसाद सेजुरी Site Investigator, स्थानीय एकीकृत विकास समाज नेपाल (सोलिड नेपाल) का तर्फबाट श्री दिना प्रधान, Acting Executive Director र डा. कृष्ण गोपाल महर्जन, Country Co-PI बीच मिति २०७९।०७।२७ तदनुसार १३ नोभेम्बर २०२२ मा चीनको RecBio Pharmaceuticals Company ले उत्पादन गरेको कोभिड-१९ विरुद्धको खोप CHO Cell को नेपालमा तेश्रो चरणको अनुसन्धान A multicenter, randomized, double-blinded, placebo-controlled Phase III trial to evaluate the efficacy, safety and immunogenicity of the recombinant two-component COVID-19 vaccine (CHO cell) in adults aged 18 years and older परियोजना सञ्चालन गर्न MSR (Beijing) Pharmaceutical Consulting Co. Ltd. (CRO) सहितको त्रिपक्षिय सम्झौता भए अनुसार यस मनमोहन मेमोरिएल मेडिकल कलेज तथा शिक्षण अस्पताल, स्वयम्भु काठमाडौंमा मिति २०७९।०९।१२ तदनुसार २७ डिसेम्बर २०२२ देखि मिति २०८०।०२।१७ तदनुसार ३० मे २०२३ सम्म र मिति २०८०।०२।१८ तदनुसार १ जुन २०२३ देखि मिति २०८०।०७।२९ तदनुसार १५ नोभेम्बर २०२३ सम्ममा नेपाल स्वास्थ्य सेवा सहकारी संस्था लिमिटेड (NEHCO) ले नै सञ्चालन गरेको मनमोहन अस्पताल दहचोक, काठमाडौंमा सम्पन्न गरिएको क्लिनिकल अध्ययन खोपका सहभागीहरूको विवरण रहेको फाईल (Source Documents) १००५ थान, सुसूचित सहमति पत्र (Informed Consent) रहेको फाईल १००५, खोपमा सहभागी हुन नसकेका (Screening Failure) व्यक्तिहरूको विवरणहरू रहेका ८८ थान फाईल, अध्ययन सम्बन्धीका विविध विवरणहरू रहेका कागजातहरूका १७६ फाईलहरू सहितको यसैसाथ संलग्न सूची (Check List) बमोजिम रूजु गरी १५ वटा टीनका बाकसमा राखेर तालाबन्दी गरी सिलबन्दी समेत गरी अन्तिम सहभागीको अन्तिम भिजिटको ५ वर्षसम्म सुरक्षित राख्नका लागि अस्पतालले उपलब्ध गराएको सुरक्षित स्थलमा उल्लिखित कागजातहरू ICH-GCP द्वारा निर्धारण गरिएको प्रचलित मापदण्ड बमोजिम Investigator को निगरानीमा रहने र प्राकृतिक विपद् बाहेकका कुनैपनि कारणबाट उल्लिखित कागजपत्रहरू हराएमा, बिग्रिएमा वा नासिएमा अस्पताल पुर्णरूपमा जिम्मेवार रहनेछ भनी तपशीलका साक्षीहरूको रोहबरमा यो भरपाई गरिलियो दियो।

ईति सम्बत् २०८१ साल भाद्र २ गते रोज १ शुभम् ।

सामान बुझाउने

दायाँ

बायाँ

हस्ताक्षर -

[Signature]



नाम — अजित आचार्य

Project Coordinator, SOLID Nepal

साक्षी

नाम

डा. खेम बहादुर कार्की

Country PI, CHO-Cell, SOLID Nepal

डा. केदार प्रसाद सेजुरी

Site Investigator (Site 1003), CHO-Cell, MMCTH



सामान बुझिलिने

दायाँ

बायाँ

हस्ताक्षर -

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नाम — डा. रामकुमार अधिकारी

Coordinator, Manamohan Hospital, Kathmandu

हस्ताक्षर

दायाँ

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LIST OF BOX/TRUNK CONTENTS

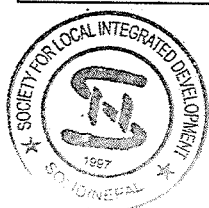
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3	CHO Cell Vaccine Trial - Worksheet	120
4	CHO Cell Vaccine Trial - Worksheet	119
5	CHO Cell Vaccine Trial - Worksheet	224
6	CHO Cell Vaccine Trial - Worksheet	75
7	CHO Cell Vaccine Trial - Worksheet	80
8	CHO Cell Vaccine Trial - Worksheet	85
9	CHO Cell Vaccine Trial - Worksheet	72
10	CHO Cell Vaccine Trial - Worksheet	72
11	Consent form (ICF V1.0)	62 files
11	Reconsent form (ICF V2.1)	8 files
12	Reconsent form (ICF V2.1)	49 files
13	ICF of screening failure	39 files
14	Worksheet of screening failure	49 files
15	51 types of files/folders/registers	176 files
	Total Worksheet	1005
	Total ICF (V1.0)	1005
	Total ICF (V2.1)	1005
	Total Screening Failure ICF (1 folder contains documents of multiple participants)	39 Folders
	Total Screening Failure Worksheet (1 folder contains documents of multiple participants)	49 Folders
	Others/ Miscellaneous files/folders/registers	176 files



Box : 1
Source Document File List (CHO Cell) Site 1003

BOX 1

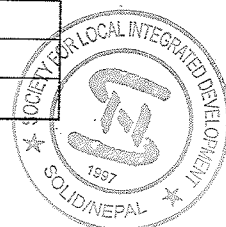
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8	100300009	48	100300071
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18	100300027	58	100300086
19	100300028	59	100300087
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36	100300054	76	100300107
37	100300055	77	100300109
38	100300056	78	100300110
39	100300058	79	100300111
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Box : 2
Source Document File List (CHO Cell) Site 1003

BOX 2

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28	100300143	68	100300190
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31	100300146	71	100300194
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34	100300150	74	100300197
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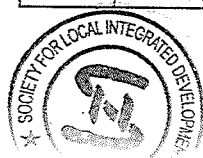
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Source Document File List (CHO Cell) Site 1003

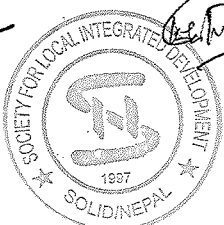
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13	100300217	53	100300274	93	100300323
14	100300218	54	100300275	94	100300325
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16	100300220	56	100300277	96	100300327
17	100300221	57	100300278	97	100300328
18	100300222	58	100300279	98	100300329
19	100300224	59	100300280	99	100300331
20	100300225	60	100300281	100	100300332
21	100300226	61	100300283	101	100300335
22	100300227	62	100300285	102	100300336
23	100300228	63	100300286	103	100300337
24	100300229	64	100300287	104	100300339
25	100300230	65	100300289	105	100300340
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28	100300236	68	100300292	108	100300345
29	100300237	69	100300293	109	100300350
30	100300238	70	100300294	110	100300351
31	100300239	71	100300295	111	100300352
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33	100300241	73	100300297	113	100300354
34	100300250	74	100300298	114	100300357
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37	100300253	77	100300304	117	100300363
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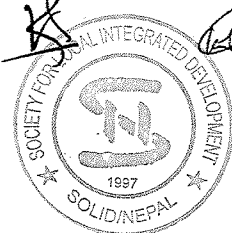
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Source Document File List (CHO Cell) Site 1003

BOX 4

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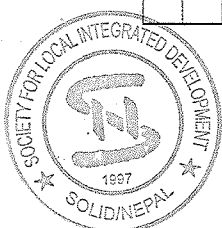
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Box : 5
Source Document File List (CHO Cell) Site 1003

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6	100300682	46	100300742	86	100300811	126	100300872	166	100301117	206	100301168		
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9	100300685	49	100300747	89	100300816	129	100300875	169	100301121	209	100301171		
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11	100300689	51	100300751	91	100300822	131	100300878	171	100301123	211	100301174		
12	100300691	52	100300752	92	100300827	132	100300879	172	100301124	212	100301175		
13	100300692	53	100300754	93	100300830	133	100300880	173	100301125	213	100301176		
14	100300693	54	100300755	94	100300835	134	100300881	174	100301126	214	100301178		
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16	100300695	56	100300757	96	100300838	136	100300883	176	100301129	216	100301181		
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19	100300699	59	100300760	99	100300842	139	100300888	179	100301136	219	100301187		
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21	100300701	61	100300762	101	100300846	141	100300895	181	100301138	221	100301189		
22	100300702	62	100300763	102	100300847	142	100300897	182	100301139	222	100301190		
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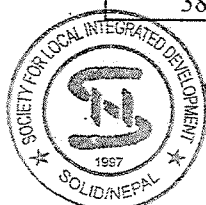
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Box : 6
Source Document File List (CHO Cell) Site 1003

BOX 6

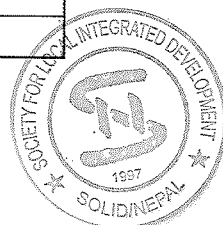
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11	100300574	49	100300636
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29	100300603	67	100300663
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33	100300608	71	100300667
34	100300610	72	100300668
35	100300612	73	100300669
36	100300614	74	100300671
37	100300616	75	100300672
38	100300618		



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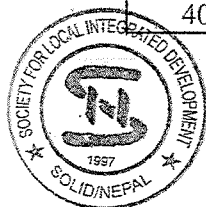
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Box : 7
Source Document File List (CHO Cell) Site 1003

BOX 7

SN	Participant ID	SN	Participant ID
1	100301194	41	100301247
2	100301195	42	100301248
3	100301199	43	100301253
4	100301200	44	100301255
5	100301201	45	100301256
6	100301202	46	100301257
7	100301205	47	100301258
8	100301206	48	100301259
9	100301207	49	100301260
10	100301208	50	100301261
11	100301209	51	100301262
12	100301210	52	100301265
13	100301211	53	100301266
14	100301213	54	100301267
15	100301214	55	100301270
16	100301215	56	100301271
17	100301217	57	100301274
18	100301219	58	100301275
19	100301220	59	100301276
20	100301221	60	100301277
21	100301222	61	100301278
22	100301223	62	100301279
23	100301225	63	100301280
24	100301226	64	100301282
25	100301227	65	100301283
26	100301228	66	100301286
27	100301229	67	100301287
28	100301230	68	100301288
29	100301231	69	100301289
30	100301233	70	100301291
31	100301234	71	100301292
32	100301235	72	100301293
33	100301237	73	100301295
34	100301238	74	100301296
35	100301239	75	100301300
36	100301241	76	100301301
37	100301242	77	100301302
38	100301244	78	100301304
39	100301245	79	100301306
40	100301246	80	100301310



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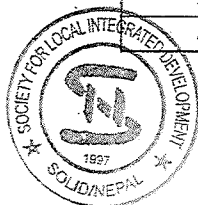
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Box : 8
Source Document File List (CHO Cell) Site 1003

BOX 8

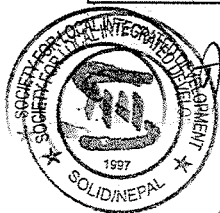
SN	Participant ID	SN	Participant ID
1	100301311	44	100301360
2	100301312	45	100301361
3	100301313	46	100301362
4	100301314	47	100301363
5	100301315	48	100301365
6	100301317	49	100301369
7	100301318	50	100301370
8	100301319	51	100301373
9	100301321	52	100301374
10	100301322	53	100301375
11	100301323	54	100301376
12	100301324	55	100301379
13	100301325	56	100301380
14	100301326	57	100301381
15	100301327	58	100301382
16	100301328	59	100301383
17	100301329	60	100301384
18	100301331	61	100301385
19	100301332	62	100301386
20	100301333	63	100301387
21	100301334	64	100301388
22	100301335	65	100301389
23	100301336	66	100301390
24	100301337	67	100301391
25	100301338	68	100301392
26	100301339	69	100301393
27	100301340	70	100301394
28	100301341	71	100301396
29	100301342	72	100301399
30	100301343	73	100301400
31	100301344	74	100301401
32	100301345	75	100301402
33	100301346	76	100301405
34	100301347	77	100301406
35	100301348	78	100301407
36	100301350	79	100301408
37	100301351	80	100301409
38	100301354	81	100301410
39	100301355	82	100301411
40	100301356	83	100301413
41	100301357	84	100301415
42	100301358	85	100301417
43	100301359		



Box : 9
Source Document File List (CHO Cell) Site 1003

BOX 9

SN	Participant ID	SN	Participant ID
1	100300901	37	100300946
2	100300902	38	100300947
3	100300904	39	100300949
4	100300905	40	100300950
5	100300906	41	100300951
6	100300907	42	100300952
7	100300908	43	100300953
8	100300910	44	100300954
9	100300911	45	100300955
10	100300912	46	100300958
11	100300913	47	100300959
12	100300914	48	100300960
13	100300915	49	100300961
14	100300917	50	100300962
15	100300920	51	100300963
16	100300921	52	100300965
17	100300922	53	100300966
18	100300923	54	100300967
19	100300925	55	100300968
20	100300926	56	100300969
21	100300928	57	100300970
22	100300929	58	100300971
23	100300930	59	100300972
24	100300931	60	100300973
25	100300932	61	100300974
26	100300933	62	100300976
27	100300934	63	100300977
28	100300935	64	100300978
29	100300936	65	100300981
30	100300937	66	100300982
31	100300938	67	100300983
32	100300939	68	100300984
33	100300942	69	100300985
34	100300943	70	100300987
35	100300944	71	100300988
36	100300945	72	100300989



Box : 10
Source Document File List (CHO Cell) Site 1003

BOX 10

SN	Participant ID	SN	Participant ID
1	100300990	37	100301043
2	100300991	38	100301044
3	100300993	39	100301045
4	100300994	40	100301046
5	100300997	41	100301047
6	100300999	42	100301048
7	100301005	43	100301049
8	100301010	44	100301050
9	100301011	45	100301052
10	100301014	46	100301053
11	100301015	47	100301054
12	100301016	48	100301057
13	100301017	49	100301058
14	100301018	50	100301060
15	100301020	51	100301061
16	100301021	52	100301062
17	100301023	53	100301064
18	100301024	54	100301065
19	100301025	55	100301066
20	100301026	56	100301067
21	100301027	57	100301068
22	100301028	58	100301070
23	100301029	59	100301071
24	100301030	60	100301072
25	100301031	61	100301075
26	100301032	62	100301076
27	100301033	63	100301077
28	100301034	64	100301078
29	100301035	65	100301079
30	100301036	66	100301080
31	100301037	67	100301082
32	100301038	68	100301085
33	100301039	69	100301089
34	100301040	70	100301090
35	100301041	71	100301091
36	100301042	72	100301092



Box : 11
Source Document File List (CHO Cell) Site 1003

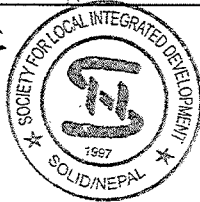
BOX 11	Consent form (ICF)	62 files
	Re-consent form (ICF)	8 files

BOX 12	Re-consent form (ICF)	49 files
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BOX 13	ICF of screening failure	39 files
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BOX 14	ICF of screening failure	49 files
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Box : 15

Source Document File List (CHO Cell) Site 1003

BOX 15-MISCELLANEOUS

S.N.	Type	Particulars	Quantity
1	Register	First dose record	5
2	Register	Third dose record	2
3	Register	Fifth visit record	1
4	Register	V4 record	1
5	Register	Pharmacy record	1
6	Register	Observation record	1
7	Register	V6 record	1
8	Register	Second dose record	2
9	Register	Medicine distribution record	1
10	Register	Good delivery record	1
11	Folder	Reconsent forms	34
12	Folder	IP transfer document	1
13	Folder	Antigen test	1
14	Folder	Diary card authorization	1
15	Folder	Participant medicine record	1
16	Folder	PCR specimen identification code	2
17	BIG folder	22.4 MVR	1
18	BIG folder	IP inventory Log	1
19	BIG folder	TMF central depot	1
20	BIG folder	investigator site file	3
21	BIG folder	24.3 others	1
22	BIG folder	Study form, log temperature, archived folder	1
23	My clear bag	Ig/igm test report	1
24	My clear bag	Diary card review	4
25	My clear bag	Observation room tracking log	4
26	My clear bag	Participant identification code list	3
27	My clear bag	Hospital record	4
28	My clear bag	Record of informed consent participant	3
29	My clear bag	Suspected/confirmed covid test list	35
30	My clear bag	Record form of participant leaving	2
31	My clear bag	SAE case reporting log	13
32	My clear bag	Temperature log	4
33	My clear bag	Vaccine number details	1
34	My clear bag	Screening and enrollment log	2
35	My clear bag	IB Brochure	1
36	My clear bag	PD management Tracker	1
37	My clear bag	Diary card athorization	1
38	My clear bag	Sample requisition form	1
39	My clear bag	DSUR	1
40	My clear bag	Pregnancy Report	2
41	My clear bag	IP receipt form	1
42	My clear bag	Protocol deviation	1
43	My clear bag	Dispensed IP	1
44	My clear bag	Rapid Antibody test	2
45	My clear bag	List of file note	1
46	My clear bag	Participant identification (Citizenship)	4
47	My clear bag	IP inventory	1



Box : 15
Source Document File List (CHO Cell) Site 1003

S.N.	Type	Particulars	Quantity
48	My clear bag	Protocol deviation	1
49	My clear bag	Equipment manual	1
50	My clear bag	Rapid antigen test	2
51	Recode file	Participant hospital treatment files	14



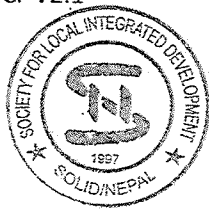
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CONTENTS OF ICF FOLDERS

1. Sign ICF V1.0
2. Identity of Participants (Copy of Citizenship)
3. Authorization for filling Diary Card
4. Sign ICF V2.1

Signature



Signature

Signature

Signature



CONTENTS OF SOURCE DOCUMENT-FOLDER

Contents of Source Documents

- V1- Worksheet
- V2- Worksheet
- V3- Worksheet
- V6- worksheet
- V7 – worksheet
- V8 – Work sheet
- V9 – Worksheet
- Participant File binder list
- Participant Identity form
- ICF recon sent form
- RT-PCR test report
- Rapid Antibody test report
- UPT test (Only female)
- IP dispensing log
- Randomization number slip
- KIT dispense log -1
- IP dispense log- 1
- ID dispensation, collection and preparation form -1
- IP Administration form
- Participant diary V3 (Solicited)
- Participant Diary V3 (Un solicited)
- UPT test report
- Kit dispense log –2 dose
- IP dispense log – 2 dose
- IP administration form 2 dose
- Participant diary (Solicited V2)
- Participant diary (Unsolicited V2)
- UPT test report V3
- Kit dispense log- 3 dose
- IP dispense log- 3 dose
- IP Administration form 3 dose
- Participant diary (Solicited V4)
- Participant diary (Unsolicited V4)
- AE log
- Source Document Review Form
- Completion/End of study form

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