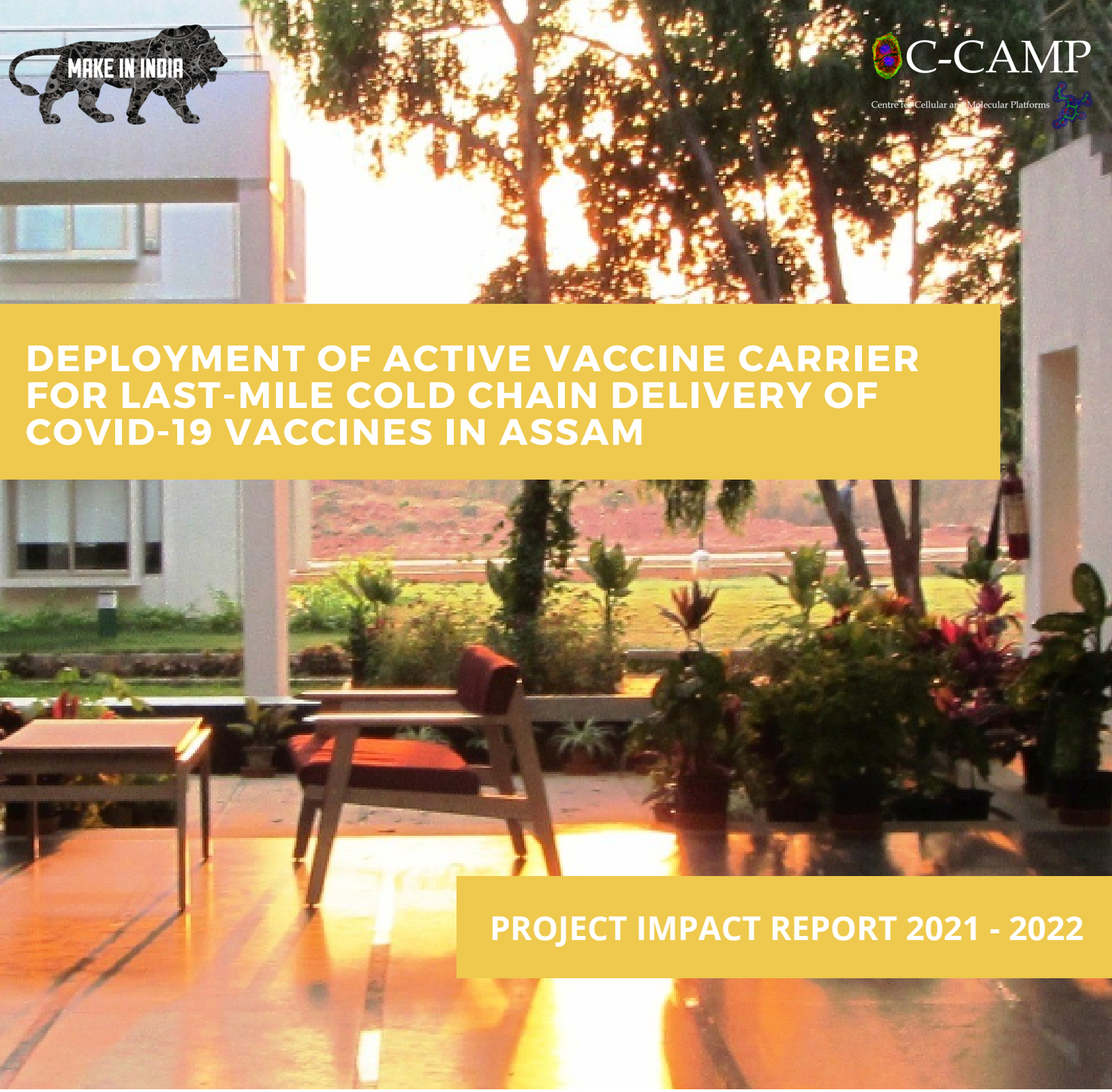

DEPLOYMENT OF ACTIVE VACCINE CARRIER FOR LAST-MILE COLD CHAIN DELIVERY OF COVID-19 VACCINES IN ASSAM

PROJECT IMPACT REPORT 2021 - 2022

HOST ORGANISATION

C-CAMP

Centre for Cellular and Molecular Platforms

ACKNOWLEDGEMENTS

Office of the Principal Scientific Adviser to the Government of India

Directorate of Health Services (FW), Assam

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REPORT SUMMARY

The purpose of this project was to introduce **a new cold-chain technology – an Active Vaccine Carrier**, by the name of Emvolio to certain states amidst the COVID-19 pandemic. Incubated and enabled by Centre for Cellular and molecular Platforms (C-CAMP), the Emvolio Active Vaccine Carrier was manufactured by Blackfrog Technologies, and scaled to deploy and support public health facilities in Assam and Manipur.

This report is a concise description of the **implementation, impact and the future implication** of adopting Emvolio active vaccine carrier for integration with public health sectors.

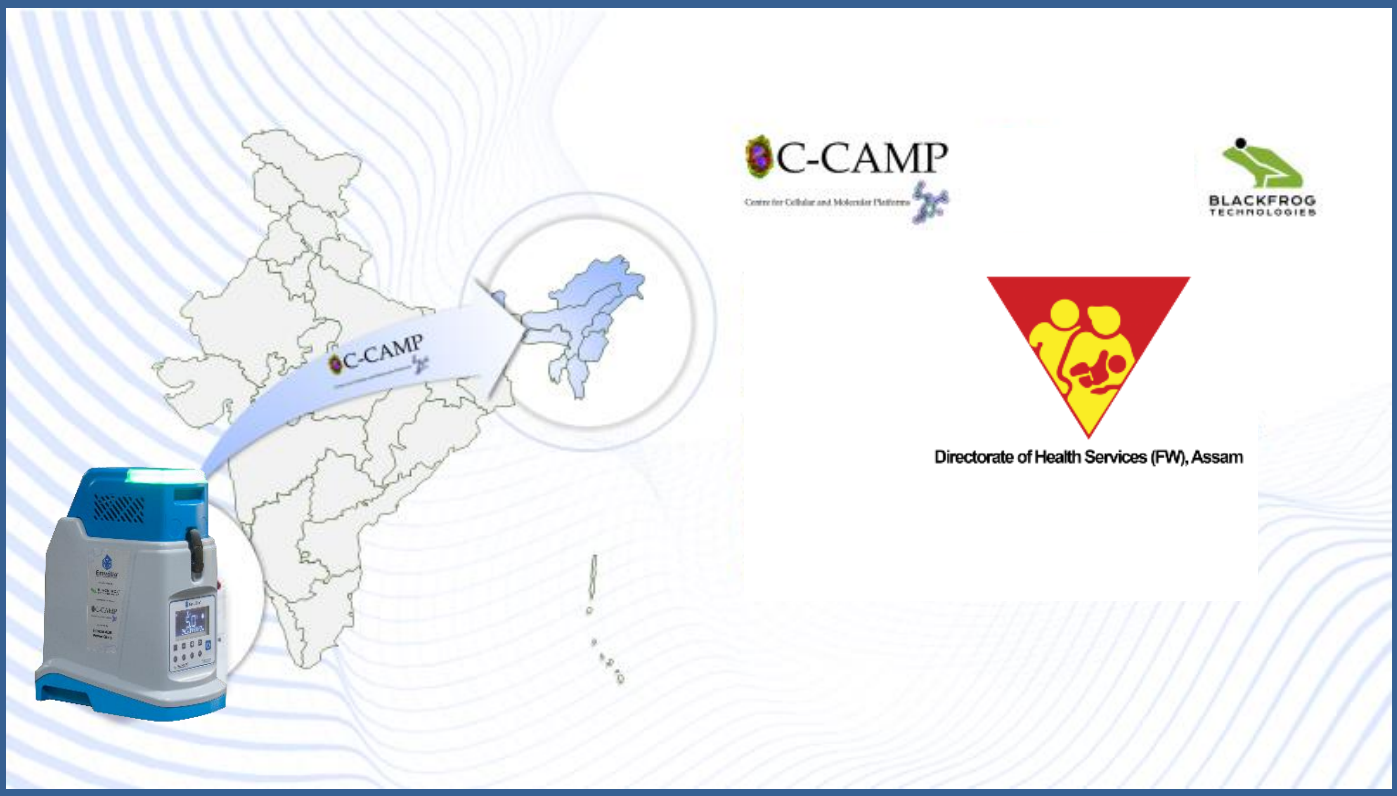
- 50 Emvolio Vaccine Carriers were deployed in 6 districts, with a distribution of 5 devices per PHCs
- Cold-Chain Technicians and healthcare workers (Auxiliary nurse midwife - ANMs) were successfully trained on the utilisation of these new devices.
- Initial adoption challenges included administrative schedules, apprehension towards technology and reluctance to try something new even if better and more efficient.
- Need for a solar-powered, portable, battery-operated vaccine carrier was strongly established based on the field surveys conducted by C-CAMP.
- Common challenges faced by ANMs in the field included poor connectivity, remote areas, intermittent or no electrical supply and limitations for long outreach programs.
- Need for new vaccination and immunization protocol proposed in case study section

The Emvolio Active Vaccine Carrier addresses the following needs in the field –

- Poor or no electrical supply – it is compatible with solar
- Strict temperatures of 2 to 8 °C across drastic ambient temperatures
- Efficient management through IoT -based technology
- Temperature monitoring without data loggers
- Portability in difficult terrains
- Weatherproofing to meet the diverse climate across Indian regions
- Easy to operate, positive end-user training and capacity building
- Scaled-down routine and operating protocol for maintenance of vaccine carriers
- Multi-functional beyond COVID-19 – Capacity for multiple types of biological samples and specimens, routine immunization, and so on.

In conclusion, the deployment was successful and the mark of disruptive innovation in public health system strengthening. The adoption of a validated, impact-driven, technology solution like Active Vaccine Carrier is achieved through the support of public health authorities. This is required to enable successful integration of innovation in to public health facilities. This is critical for the improvement in health outcomes, including moving the needle towards better indicators in Maternal Child healthcare.

Contents



With the support and cooperation from Directorate of Health Services & Family Welfare, Guwahati, Assam, 50 units of Blackfrog Technologies' Emvolio Active Vaccine Carrier, are successfully deployed across 6 districts in Assam.

Project Summary

Scaling indigenous health technology for strengthening last-mile vaccine delivery in public health systems in India

AIM

Use of Emvólio Active Vaccine Carrier in last-mile cold chain delivery of COVID-19 vaccines in Assam

KEY OBJECTIVES

1. Deployment of 50 units of Emvólio Active Vaccine Carriers
2. Training of cold-chain technicians and ANMs
3. Impact Monitoring of deployed Emvólio devices

BENEFICIARIES

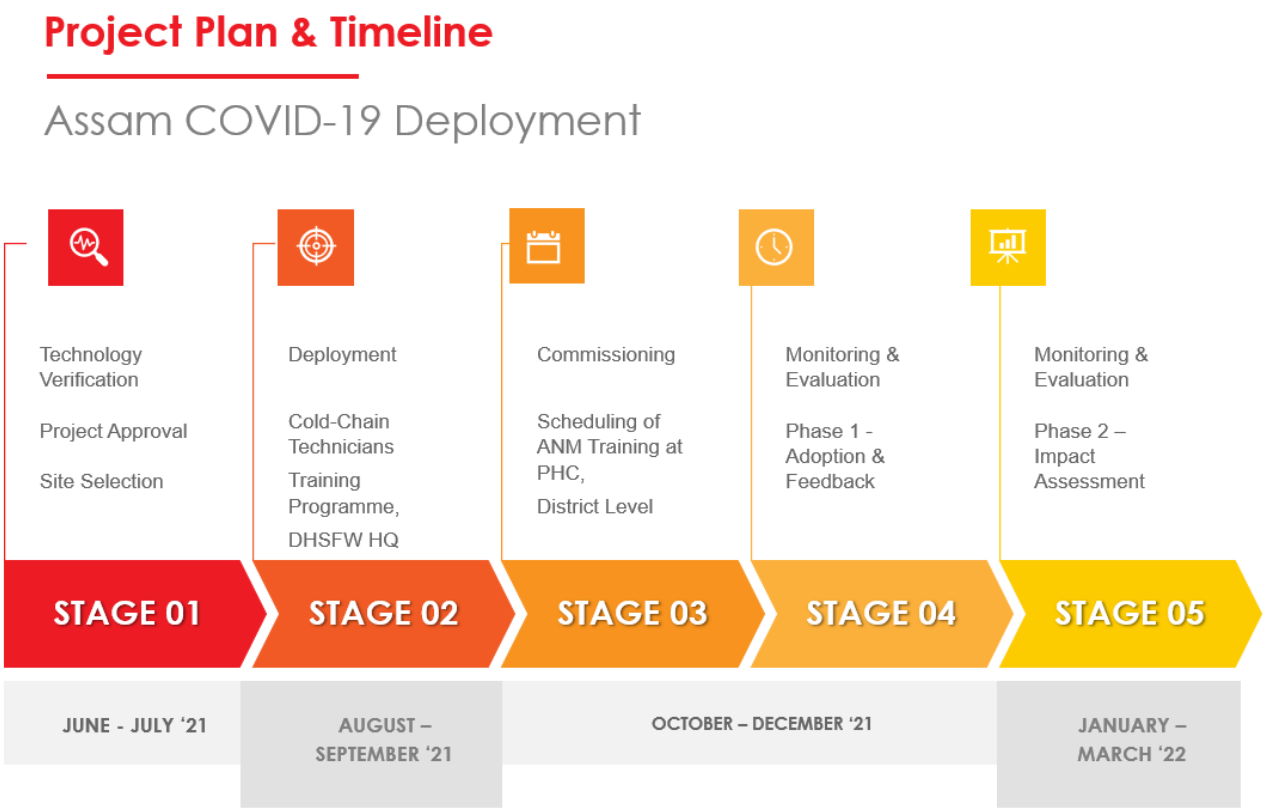
Assam | Public Health Centers and sub-centres in the Districts of Dhubri, South Salmara, Karbi Anglong, Majuli and Dima Hasao

Background

Through CCAMP's Corporate Social Responsibility (CSR) partner and incubation and acceleration platform an indigenous innovation – portable, battery operated, active vaccine carrier for last-mile safe delivery of COVID-19 vaccines - was selected for rapid deployment in the public health sector in Assam. C-CAMP had conducted due diligence processes for the innovation and technology partners through its ongoing programs, ensuring ready-to-deploy solutions are available when the opportunity to strengthen and support the nation's fight against COVID-19 arises.

Spread across varying terrains and low-resource settings, 11 Public Health Centers (PHCs) across 6 districts, were selected by the Office of Directorate of Health Services & Family Welfare (DHSFW), Guwahati, for the deployment of this innovative technology to strengthen public health infrastructure.

The deployment began in September with the shipment of 50 Emvolio Vaccine Carriers to Directorate of Health Services (Family Welfare) (DHSFW), Guwahati. The Emvolio vaccine carriers were introduced to the state vaccination program in October 2021 with the support and guidance of Mr. Munindranath M. Ngatey (Director); Dr. B. Goswami (Joint-Director (UIP), SEPIO); Dr. BK Choudhury (State Cold Chain Officer. An MoU was signed between the technology partner, Blackfrog Technologies, and DHSFW, Assam, ahead of the commissioning and technology training which took place at the DHSFW office. Project facilitation, implementation and monitoring was taken care by C-CAMP.



Project Stakeholders

Guidance & Facilitation | Office of the Principal Scientific Adviser to The Government of India (PSA)

The Office of the PSA provides pragmatic and objective advice to the Prime Minister and cabinet on matters related to science, technology and innovation with a focus on application of science and technology in critical infrastructure, economic and social sectors in partnership with Government departments, institutions and industry. This project would not have been possible without the guidance and facilitation from the Office of the PSA.

Overall Innovation, Incubation & Implementation | Centre for Cellular and Molecular Platforms (C-CAMP)

The Centre for Cellular and Molecular Platforms, or C-CAMP, an initiative supported by the Department of Biotechnology, Govt of India, has been an enabler and catalyst of cutting-edge research and innovation in the life sciences since 2009. As a part of C-CAMP's mandate of promoting entrepreneurship and innovation, C-CAMP has created and fostered an entrepreneur-friendly culture in and around Academic/Research environment through its involvement in Seed Funding Schemes for Startups, Entrepreneur Mentorship program and Bio-Incubation facility.

As an organisation dedicated to the service of the nation, C-CAMP is dedicated to ensuring that the latest products and services in life sciences impact the lives of any individual in the country regardless of their means. C-CAMP works with several reputed philanthropic agencies to provide interventions, especially in the realm of healthcare, thus enabling cutting-edge innovation to have real on-ground impact. C-CAMP builds precise indigenous innovations based on identification of problems specific to India and its public health sectors, right from primary to tertiary care. C-CAMP's Technology Impact Program receives support from various Corporate Social Responsibility partners to support funding for COVID-19 initiatives and beyond.

Government Partner | Directorate of Health Services (Family Welfare), Guwahati, Assam

The DHS(FW), under the Ministry for Health and Family Welfare, is responsible for maintaining and developing the health care system in the state and guiding and supervising the Health and Family Welfare Programme of the state. The activities of the department include establishment and maintenance of medical institutions with necessary infrastructure, implementation of National Disease Control and Eradication Programmes, Control of communicable as well as non-communicable diseases apart from various other functions.

The office has been playing a pivotal role in the country's fight against the COVID-19 pandemic, rising to the challenge and being a pioneer in facilitating and adopting innovation to combat COVID-19.

Innovation & Technology | Blackfrog Technologies

Emvólio is a portable active cooling (battery-powered) device that will provide a platform for delivery of vaccines and all other biologicals like blood, serums, viral culture which require to be kept strictly between 2°C and 8°C for 12+ hours in the field. The product has been designed in accordance with WHO PQS E003 specifications and conforms to IEC 60601 standards.

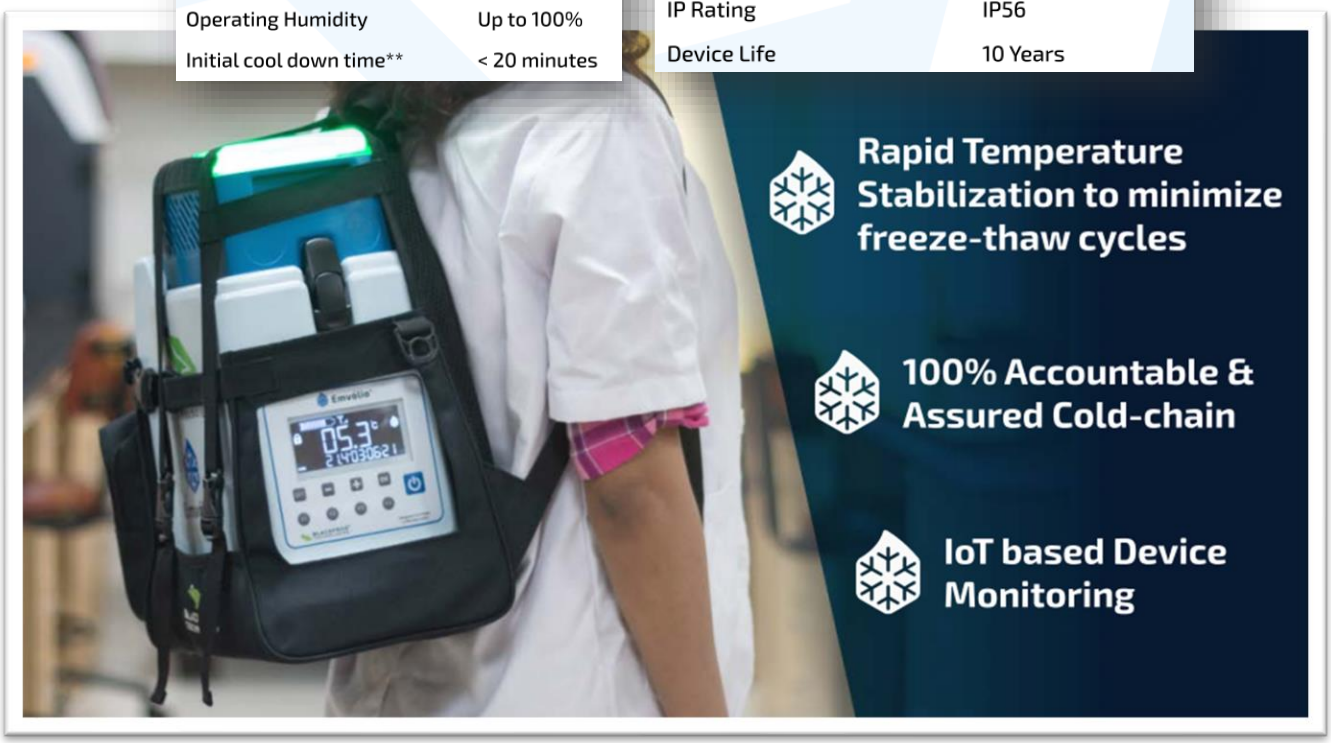
- LED and Buzzer Alerts
- Temperature Indication
- Active Cooling
- Continuous Operation when plugged in
- Portable and Lightweight
- IP56 Rated - Dust & Water Resistance
- Easy and fast charging
- Adaptable to DRE (Solar) applications

Blackfrog Technologies is an ISO 13485:2016 certified manufacturer of Medical Devices.

BLACKFROG® TECHNOLOGIES

Adjustable internal chamber Temperature Range	-10°C to 25 °C
Accuracy of maintained Temperature	±0.5°C
Operating Time*	12+ Hours
Operating ambient Temperature	-20°C to 65°C
Operating Humidity	Up to 100%
Initial cool down time**	< 20 minutes

Dimensions (L x B x H)	30cm x 20cm x 41cm
Weight	6.7 Kg
Payload Capacity	1.8 L
Battery	311Wh Li-ion
Charging Time	4 Hours
IP Rating	IP56
Device Life	10 Years



Technology Access Model for Assam

Impact Overview

EMVOLIO IMPACT NUMBERS

C-CAMP
Centre for Cellular and Molecular Platforms

6424+
COVID-19 Vaccine Doses Administered

In 57 sessions

50 Portable Active Vaccine Carriers

Deployed since October '21

COVERAGE

SUBCENTERS	232
PHCs	11
DISTRICTS	6

239
Doses of Penta, OPV, HEP-B, DPT, TT, JE
Successfully administered

Utilization for RI in 6 PHCs initiated

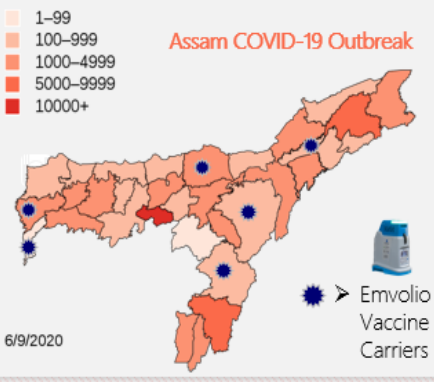
AVERAGE EMVOLIO USAGE

70%
Device Usage Weekly

52%
Contribution to COVID-19 vaccinations*

*monthly, per PHC

Deployed in 6 Districts



Impact Numbers

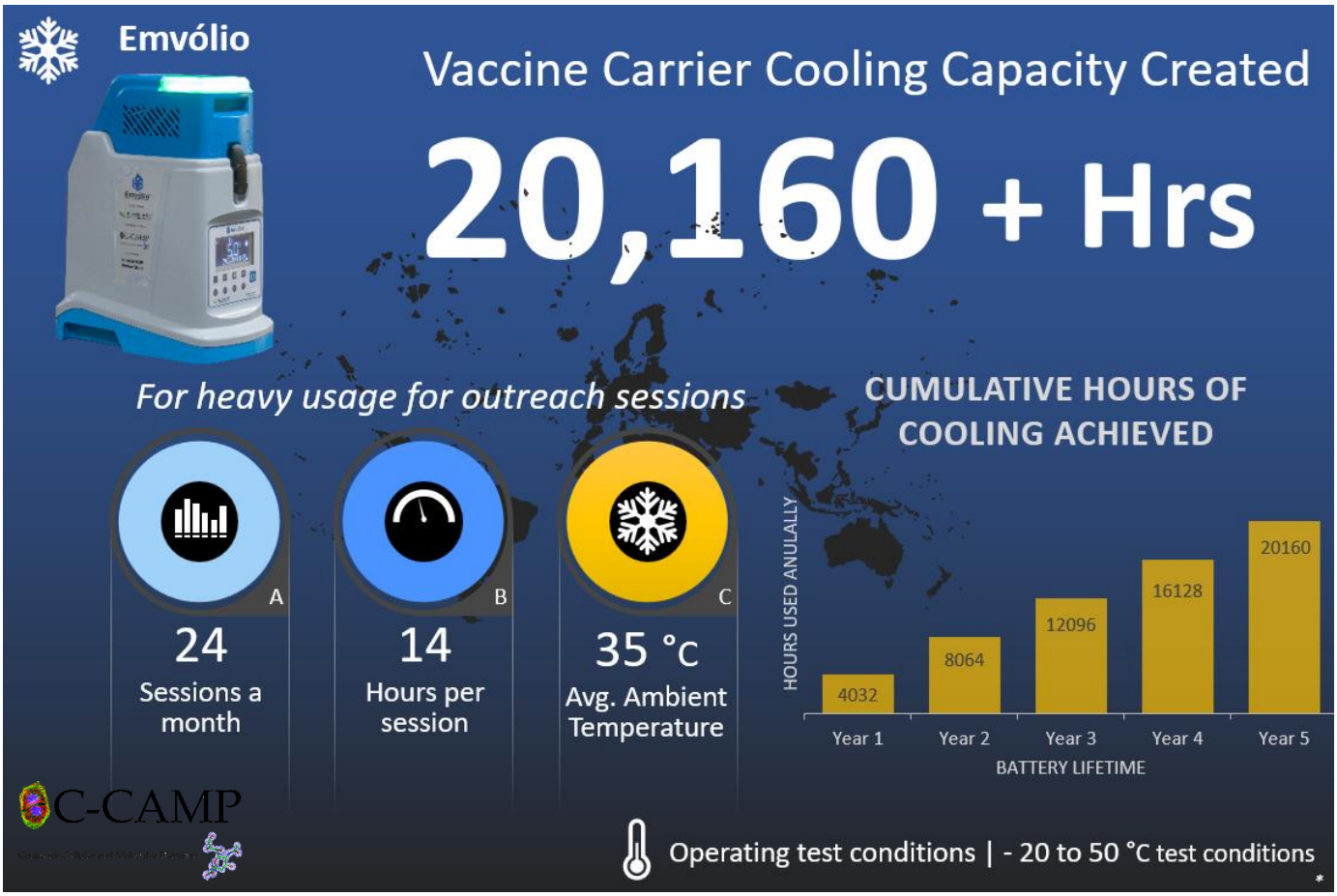
TOTAL IMPACT	Project Mid-Point (Last 3 months)	Potential Estimate for 12 months
Number of people vaccinated against COVID-19 in 6 Districts*	**6424+**	**51,392+**
Number of public health centers benefitted by Emvolio	**11**	**26**
Number of public health sub - centers potentially benefitted by Emvolio**	**232**	**604**
Number of healthcare workers trained on new active vaccine carrier technology	**103**	**1370**
No. of hours of cooling capacity provided for vaccines per device	**310**	**1238+**
Average storage capacity provided for 10ml vaccine vials per device *(Approx. 45 vials carried per session)*	3600+ vials	14,400+ vials

*****50 Emvolio vaccine carriers distributed across 6 districts. This number reflects total number of doses administered using Emvolio in the last 3 months in 3 out of 6 districts in Assam. *Numbers are still being collected for remaining 3 districts. It is expected to be 1.5 times the measured total.*

****** This reflects total number of sub-centers under the 11 PHCs selected for deployment which Emvolio can be utilised for as per the need.

Preparedness and adoption of any new technology is always critical to receiving the complete benefit envisaged at the time of innovation. C-CAMP with DHSFW, Guwahati, remain committed to working with the manufacturers on increasing access to under-served regions in Assam and supporting the adoption of critical technology in order to scale impact, beyond the pandemic.

Impact in Images



C-CAMP Programme Expertise

C-CAMP has played an integral role in achieving the milestones outlined for this project and beyond. In addition to comprehensive support for the startup with far-reaching implications, C-CAMP has contributed to the overall ecosystem surrounding innovation for scale and impact in the public health sector.

Innovation |

- C-CAMP's unique position as a technology platform brings to the world, access to innovation through its various programs that create a holistic ecosystem from discovery to innovation to acceleration and now to deployment.

- C-CAMP builds precise indigenous innovations based on identification of problems specific to India and its public health sectors, right from primary to tertiary care.

- C-CAMP nurtures these innovations for far-reaching impact and solving healthcare problems at scale in India. Consequently, the selection of the appropriate and relevant technology partners for this project at the onset of the pandemic was possible through C-CAMP's expertise in the area of innovation.

- C-CAMP had conducted due diligence processes for the innovation and technology partners through its ongoing programs, ensuring ready-to-deploy solutions are available when the opportunity to strengthen and support the nation's fight against COVID-19 arises.

Implementation & Impact Partner |

· C-CAMP's programme and project team have built process and strategy-driven templates for achieving project milestones, with the creation of weekly project level checklists, schedules, and escalation processes for technical issues in deployment and implementation. The team has provided verification for execution, outputs, and outcomes at all stages of the project.

· Facilitating Stakeholder Escalation and engagement by reaching out to different beneficiaries to provide access for deployment.

· Templates for MoUs and public-private partner agreements.

· C-CAMP was responsible for all communication and visibility across the various stakeholders involved in the project.

· Development of the framework for monitoring & evaluation and impact models. From conception to execution for research data collection from the field and continual monitoring through engagement with the beneficiaries.

· Facilitating field-driven research and impact monitoring vertical for the startup as well as for the project. Concept of case-studies was introduced to the startup with a focus on the larger picture and programme has led to access to active feedback from the end-users in the public health system.

Mentorship & Incubation |

· Provided mentorship and handholding for supply chain management, manufacturing scale-up, logistics and monitoring and evaluation of technology usage.

· Hand Holding for deployment, commissioning, and training across the different beneficiaries.

· Project templates from C-CAMP have become part of the company's internal organizational structure and data collection. C-CAMP has supported metrics for building credibility which has in turn led to expansion in marketing strategy and further product proposals.

· Provided incubation support which includes development of business scale-up strategies.

· Engineering inputs from the domain experts for problem-solving and product improvisation.

Hand holding for Industry Access & Network |

· Stepping-stone and platform for networking with a host of stakeholders such as investors, potential customers, and governmental agencies.

· C-CAMP introduced the startup to experts with industrial and academic experience to bring in technical expertise, garner credibility and work towards a roadmap for the startup's future growth.

· Provided access to mentorship for health economic cost benefit analysis for the technology.

· Access to medical experts for detailed review of the product based on their field experience and requirements. This has led to potential improvements for future versions of the product as well as delivery mechanisms in healthcare.

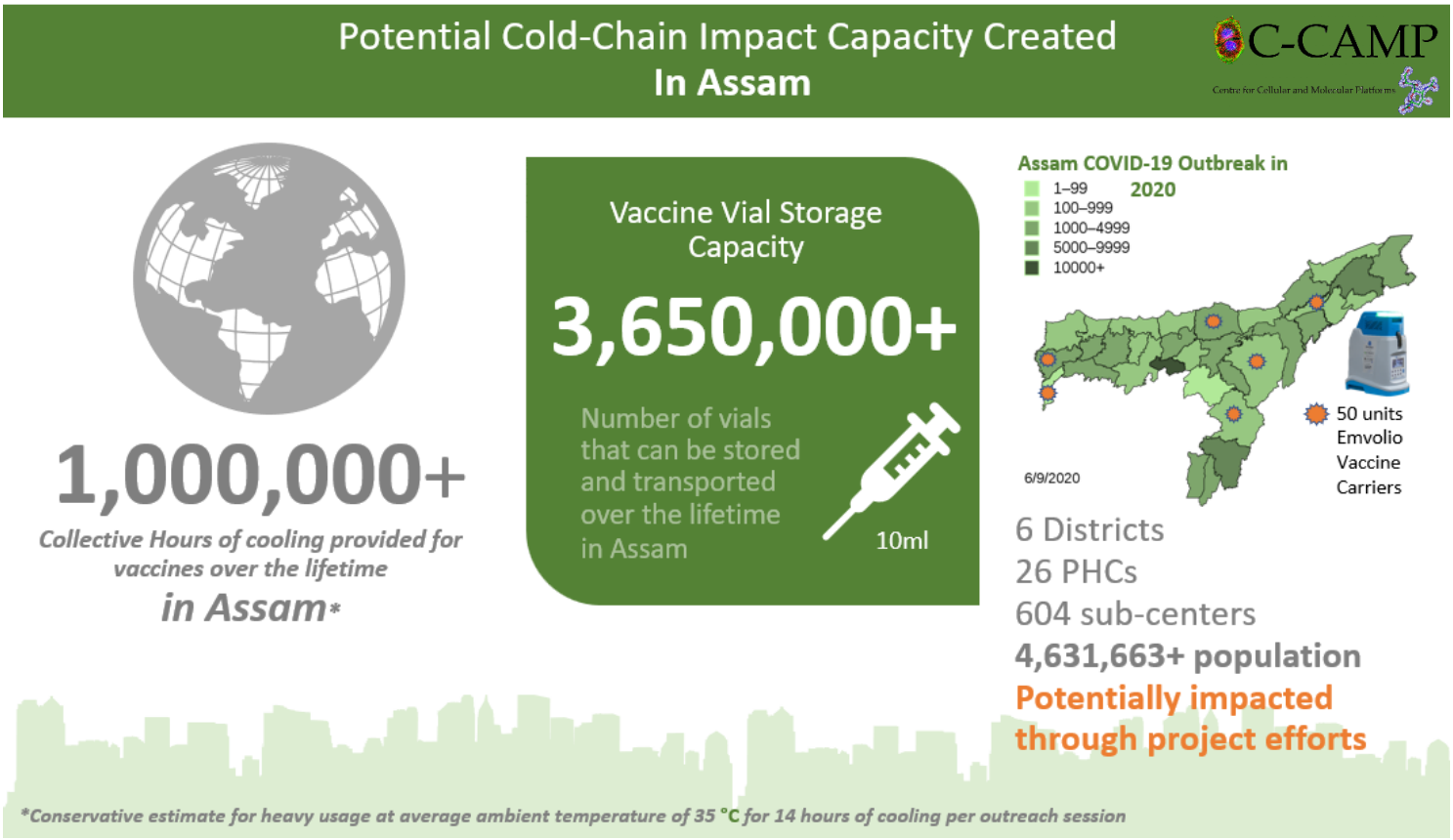
· Visibility and collateral marketing for the startup and innovation furthering private-public partnerships in the health ecosystem.

· C-CAMP brings a crucial trust factor and human dynamic responsible for facilitating cross-learnings across startups and peer to peer interaction for support and knowledge sharing.

Looking Ahead

Potential Impact Capacity

The deployment and immediate positive outcomes of the project is but a small part of what C-CAMP envisages the overall impact to be. A continued and exponential impact over the lifetime of the devices due to the capacity created through this project is expected. The potential impact over the lifetime of the product is given in the following infographics. While the project duration is 6 months, due to the rise in cases in the third wave recently and the uncertainty of the COVID-19 pandemic - vaccinations and immunization efforts can be sustained through technologies like Emvolio.



Phase 2 | +150 Emvolio Active Vaccine Carriers *(CSR-supported)* are approved for deployment in Assam to scale state-wide coverage and strengthen public health infrastructure.

Impact	Estimated number of hours of cooling for vaccines during project (6 months)	Estimated number of hours of cooling for vaccines during product lifetime (5 years)
Hours of cooling capacity created in the field by 1 device*	**2016+**	**20,160+**
Collective hours of cooling capacity created in the field by 50 devices*	**100,800+**	**1,008,000+**

*Estimated for heavy usage of 24 outreach sessions a month at an average ambient temperature of 35 °C for 14 hours of use per session, though it can hold temperature for 16+ hours in the field, vaccination sessions are currently held only for 6-8 hours in the field.
(It has been tested to maintain 5 °C temperature even at a maximum ambient temperature of 50 °C)

These are conservative estimates and the numbers are expected to be 1.5 times higher when operated moderately for 15 outreach sessions a month at an average ambient temperature of 25 °C for 14 hours of use per session, even extending product life from 5 to 7 years. The vaccine carrier can easily provide up to 24-28 hours of cooling in the field at average ambient temperatures of 25 °C and even more so as ambient temperatures dip.

Average Ambient Temperature	25 °C	35 °C
Passive Vaccine Carrier (Cooling In hours)	6	6
Emvolio Active Vaccine Carrier (Average hours of cooling*)	**18**	**12**
Vaccine Life Extended over Passive carriers	**303%**	**196%**

Over 5 years of Usage

Vaccine life gets a boost exponentially at over 300% when Emvolio active vaccine carriers are utilised in the field at average ambient temperatures of 25 °C for over 5 years and extended by over 150% when used in the field at average ambient temperatures of 35 °C for over 5 years. Current immunization schedules do not allow for the complete potential of the device to be experience. Factors like vaccine hesitancy in certain parts of the county also contribute to the low turnout of vaccinations during outreach sessions. However, maternal - childcare initiatives can greatly be benefitted with a portable, intelligent active vaccine carrier.

Emvolio's Vaccine Surveillance Model

Emvolio vaccine carrier's key feature is the MyEmvolio supporting software – Emvolio's IoT enabled - data **tracking** dashboard and **on-device display of temperature** and other indicators addresses challenges of vaccine potency and efficacy, enabling ANMs to be better informed while on the field. MyEmvolio Dashboard for monitoring and tracking activity in the field by NHM Director, Director of Immunization, State Cold Chain Officer, District Program Managers and receiving alerts on various field required characteristics is compatible for integrating with eVIN platform in the future.

The Need |

Traceability: The lack of a streamlined vaccine delivery and management system makes it challenging to trace the trajectory of vaccines along the value chain, often resulting in erroneous administration of vaccines (expired vial, wrong drug, counterfeit/recalled products, etc.), which is a threat to public health. Further, recipients are often unable to keep track of their vaccine schedules, due to human error in registering data.

Inventory Management: Current inventory management systems used by vaccine store managers often compromise on vaccine efficacy and operational efficiency because they are not integrated with vaccine administration data. For example, store managers often maintain a greater-than-optimal stock, which increases the likelihood of compromised efficacy due to external factors such as power outages, expiry, etc.

Roadmap |

Blackfrog's goal is to develop an Advanced Immunization Management System (AIMS), which will enable sophisticated networking and data management capabilities, which in turn contribute to enhancing immunization coverage, traceability, and inventory management. Blackfrog's team aim to achieve this by integrating AIMS with the Government of India's Electronic Vaccine Intelligence Network (eVIN) portal, expanding the latter's capabilities beyond cold-chain management, to systemic immunization management. Further, the goal is to build an immunization database that feeds inputs back to the system, with the aim of continuous refinement.

Target Beneficiaries |

1. Vaccine store managers: Inefficiencies and losses are minimized.
2. Healthcare providers: Vaccine delivery and management processes are significantly simplified, reducing the margin of error.
3. Recipients: Simplified processes and reduced margin of error lead to higher standards of safety. It would enable efficient delivery and management of vaccines (and biologicals for testing), reducing the overall burden on the public healthcare ecosystem.

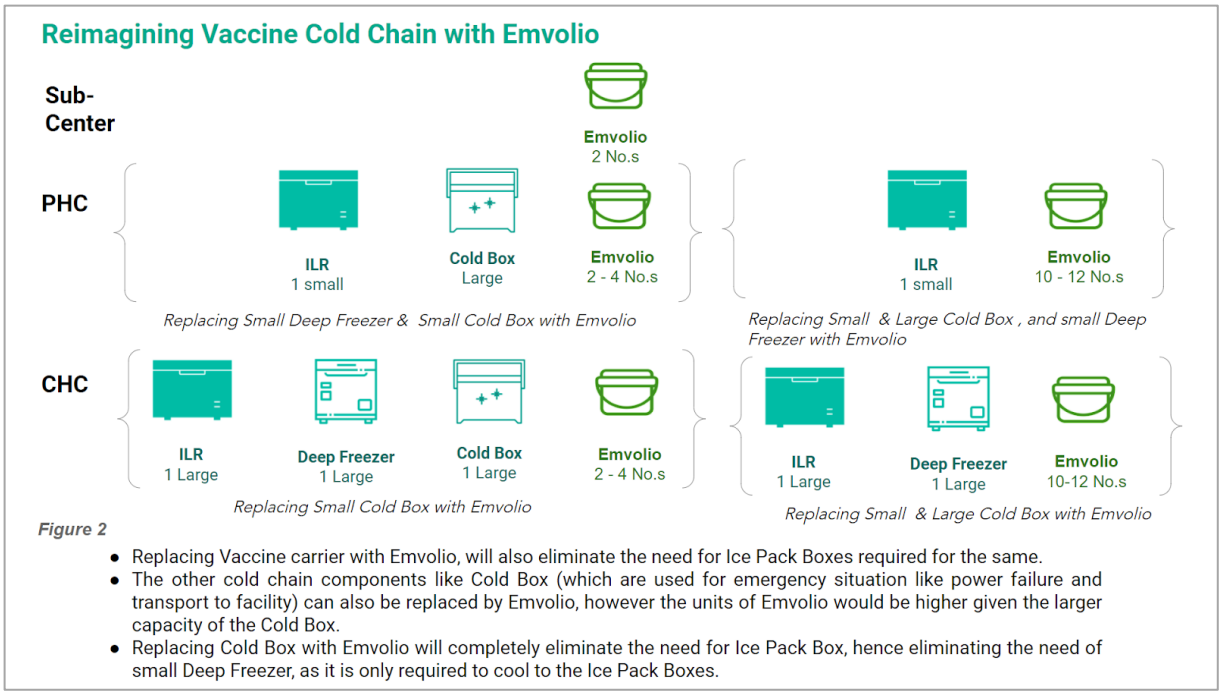
Meeting SD3 goals through SD7 | Energy Model

Emvolio as a **solar powered**, **battery-operated** device provides a critical **health energy nexus** much required in the remote regions with intermittent power supply and can operate as a stand-alone refrigerator at a lower power consumption, reducing the need for ILRs and larger refrigeration units in Public Health Centers & sub-centres *(Currently being used in that manner as per the need in Fakirganj Model Hospital, Dhubri District, Assam)*.

While there are plenty of solutions available for the areas with at least partial access to electricity, the vaccine storage and transportation for off-grid areas remains challenging. According to **Assam's State Cold Chain Officer,** there are thousand**s** health posts in remote off-grid areas. The big challenges are: the reliable long-term storage devices that can keep vaccines within safe temperature range; and the logistics of ice and vaccines to support both vaccine distribution and outreach**, accessing communities in very-hard-to-reach areas.**

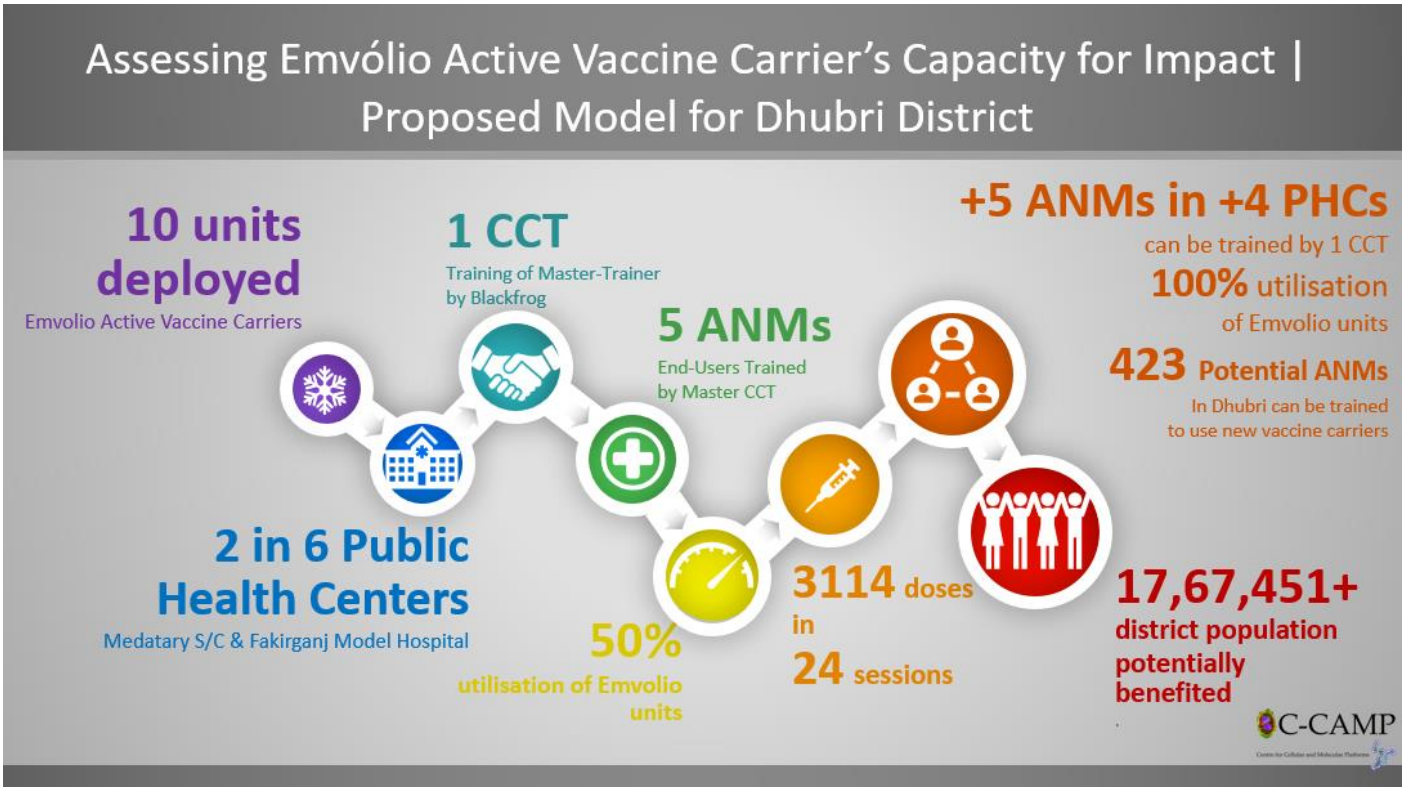
For Blackfrog's Emvolio, a 100W solar panel is sufficient to power the system with ample margin. The team's technical advisors are in the process of exploring compatibility with portable solar carriers, ensuring even further increase in cooling hours provided on the field.

SELCO Foundation, a pioneer and key enabler for off-the-grid, resilient and distributed renewable energy systems, is exploring the benefit to cost and energy via active carriers like Emvolio. **The current project is ongoing.**



Source: SELCO Foundation, Bangalore, India (2021)

Model for Scaling and Deployment of healthcare technology |



It is vital to the nation to upgrade healthcare infrastructure through deploying cutting edge healthcare innovations at scale to ensure the continuing evolution and transformation of the healthcare sector that will enable better healthcare, more affordable care and save lives.

The healthcare sector is highly regulated at state and national levels. Health infrastructure in India is largely publicly funded, and to ensure that the technologies reach the maximum number of people from excluded communities, geographies, and socio-economic background it is vital to work with the government sector for meaningful and lasting impact.

While effective, the healthcare system is a challenge to deal with for smaller companies, startups and even philanthropic agencies that aim to carry out positive interventions. This is where there is a need for a district-level and a country-wide model, with the relevant expertise to deploy and scale the model.

The institutional frameworks of cold-chain and healthcare are vast and only change very slowly over years. The pace at which healthcare innovations need to be deployed is very fast. The faster technologies are deployed, more lives are saved, and more people live healthy lives. Thus, while policy changes and systemic changes will take place in due course, the need to deploy quickly within the system is necessary to enable policy changes and this has been further highlighted by the COVID-19 pandemic.

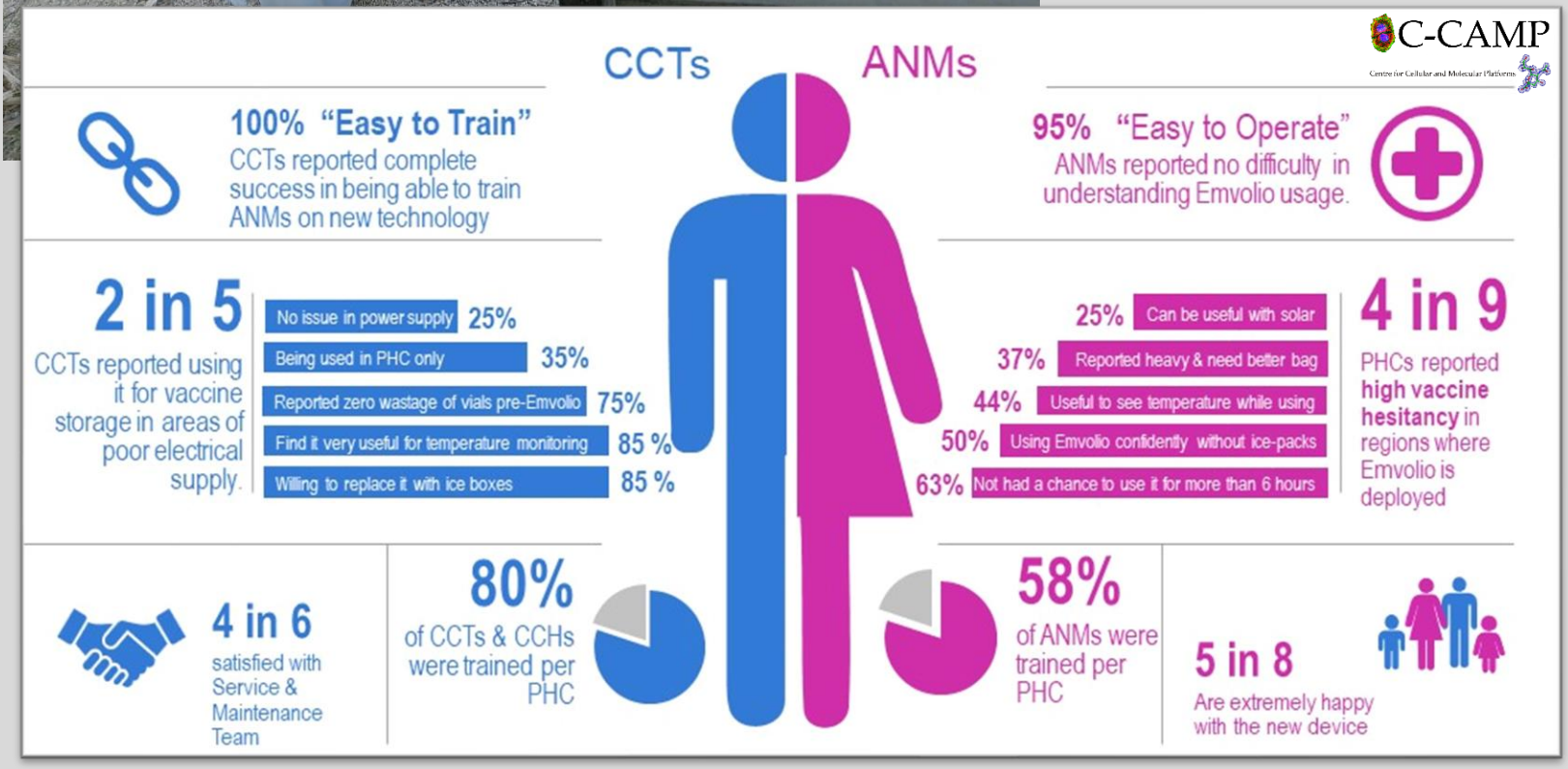
To deploy quickly there is a strong need for:

1. Strong partnerships and network across the country
2. Experience in dealing with healthcare stakeholders
3. Experience in project management
4. Understanding of the healthcare scenario in terms of need, administration, and regulation
5. Access to the latest cutting-edge innovations and expertise to gauge their effectivity
6. A strong institution with ties to leading scientific and industrial offices of the nation

It is through these strengths that the C-CAMP team has created a model for technological deployment at scale. This is done with in-house protocols and an experienced team that will ensure a project is deployed despite several challenges that is presented by the ecosystem and value-chain.

Refer more details
Page 8 – Assam Deployment Model
Page 19 – Deployment Report
Page 27 – Technology Adoption
Page 28 - Learnings

Deployment Report



Capacity Building

DISTRICT	South Salmara Mancachar	Dhubri		Majuli	
Name of Public Health Centre	South Salmara PHC	Medartary S/D	Fakirganj Hospital	Ratanpur Miri PHC	Karatipar, Kamalabari PHC
Total Trained ANMs / MPWs at site PHC and connected Sub-Centers	6	8	3	6	6
Number of ANMs / MPWs trained for Emvolio	6	3	2	7	6
Percentage of CCTs & CCHs trained for Emvolio*	100%	33%		100%	
Total District Capacity for ANMs / MPWs for Emvolio**	**76**	**428**		**93**	

***Percentage of CCTs & CCHs trained for Emvolio –** *Each district has 1 – 2 Cold-Chain Technicians and each PHC has minimum 1 cold-chain handler. This is the number of CCTs / CCHs per site that received training directly from the technology partner during deployment as part of the master-training plan, for the 6 selected districts.*

*** Total District Capacity for ANMs / MPWs for Emvolio -** *This includes the total number of ANMs, additional ANMs and MPWs available per district who can receive training and utilize Emvolio based on work shifts, outreach sessions and ease of portability of the device. The number of healthcare workers who initially received training from the cold-chain technicians and remote support from the technology partner during deployment can compound easily with the current capacity building plan.*

DISTRICT	Karbi Anglong		Dima Hasao		Sonitpur	
Name of the Centre	Dhansiri PHC	Chowkihola PHC	Diyungmukh PHC	Gunjung PHC	Dhekiajuli BPHC	Jamugurihat SHC
Total Trained ANMs / MPWs at site PHC and connected Sub-Centers	10	4	13	17	87	26
Percentage of CCTs & CCHs trained for Emvolio	100%		100%		67%	
Number of ANMs / MPWs trained for Emvolio*	10	4	7	8	26	24
Total District Capacity for ANMs / MPWs for Emvolio**	**243**		**173**		**357**	

***Percentage of CCTs & CCHs trained for Emvolio** – Each district has 1 – 2 Cold-Chain Technicians and each PHC has minimum 1 cold-chain handler. This is the number of CCTs / CCHs per site that received training directly from the technology partner during deployment as part of the master-training plan, for the 6 selected districts.*

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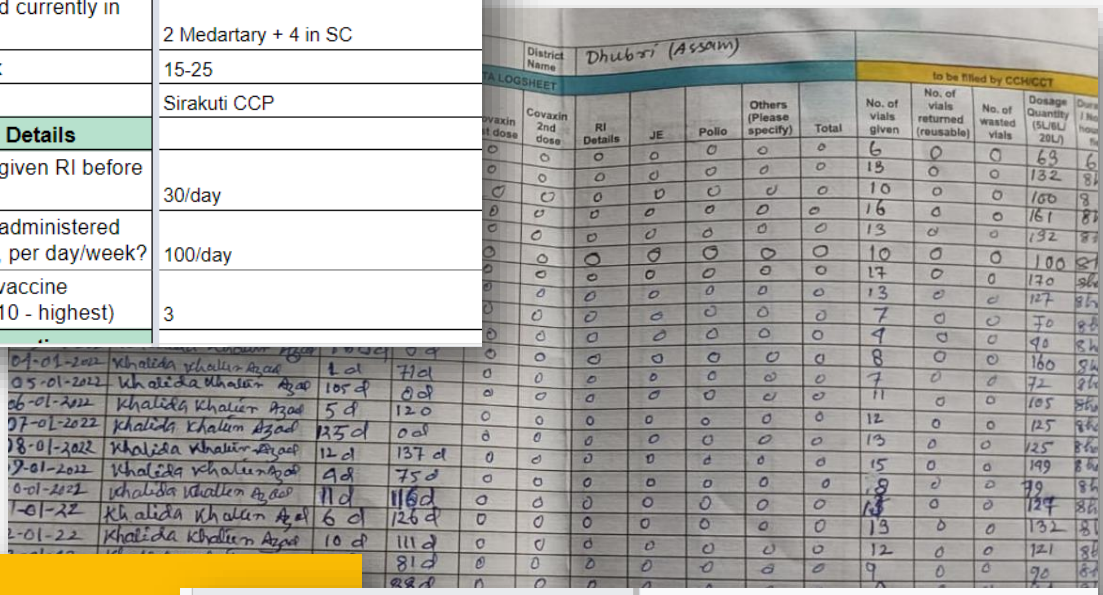
DISTRICT	Dhubri		Sonitpur	
Name of the Centre	Medartary	Fakirganj Hospital	Dhekiajuli	Jamugurihat
Population & Vaccination Details				
In this district, what is the scale of vaccine hesitancy *(Rate from 1 - lowest to 10 - highest)*	3	2	3	3
On an average, how many people administered COVID-19 vaccines using passive carriers, per day?	100	60	100	100
On an average, how many children given RI with passive carriers, per day?	30	30	90	22
Type of vaccinations being given at centre	COVID, RI	COVID, RI, JE	COVID, RI, JE	COVID, RI, JE
Total no. of doses administered by PHC – COVID-19 (Nov-Dec)	Nov -1987 Dec -1183	Nov - 3728 Dec - 3156	Nov - 900 Dec - 697	Nov -199 Dec - 100
Total no. of doses administered by PHC – RI (Nov-Dec)	Nov - 26	Nov 356 Dec 183	Nov - 101 Dec - 83	Nov - 42 Dec - 21
No. of COVID-19 vaccinations with Emvolio	**659**	**2455**	**298**	**42**
Monthly Coverage with Emvolio	**56%**	**78%**	**43%**	**42%**
Per Day Average COVID-19 doses administered using Emvolio	**132**	**129**	**50**	**14**
No. of COVID-19 sessions completed with Emvolio	5	19	6	3
No. of RI sessions with Emvolio	16	36	0	152
No. of JE sessions with Emvolio	-	5	-	30

Technology Adoption & Monitoring Record Samples

PHC Name, District	Medartary SD, Dhubri
Schedule/Program	
What is the weekly schedule for Routine Immunizations?	Wednesday
What is the weekly schedule for COVID-19 Vaccinations?	Everyday
RI administered here	No
Covishield or Covaxin administered here	Covishield
Cold Chain Equipment Details	
Mention PHCs & SCs ANM connected to	Medartary SD / Nayaparowa SC
How many iceboxes are being used currently in the PHCs/SCs?	2 Medartary + 4 in SC
How many vials carried per ice box	15-25
Nearest cold chain storage point	Sirakuti CCP
Population & Vaccination Details	
On an average, how many people given RI before Emvolio, per day/week?	30/day
On an average, how many people administered COVID-19 vaccine before Emvolio, per day/week?	100/day
In this district, what is the scale of vaccine hesitancy (Rate from 1 - lowest to 10 - highest)	3



COVID-19 Vaccinations Def
Administered using Emvo

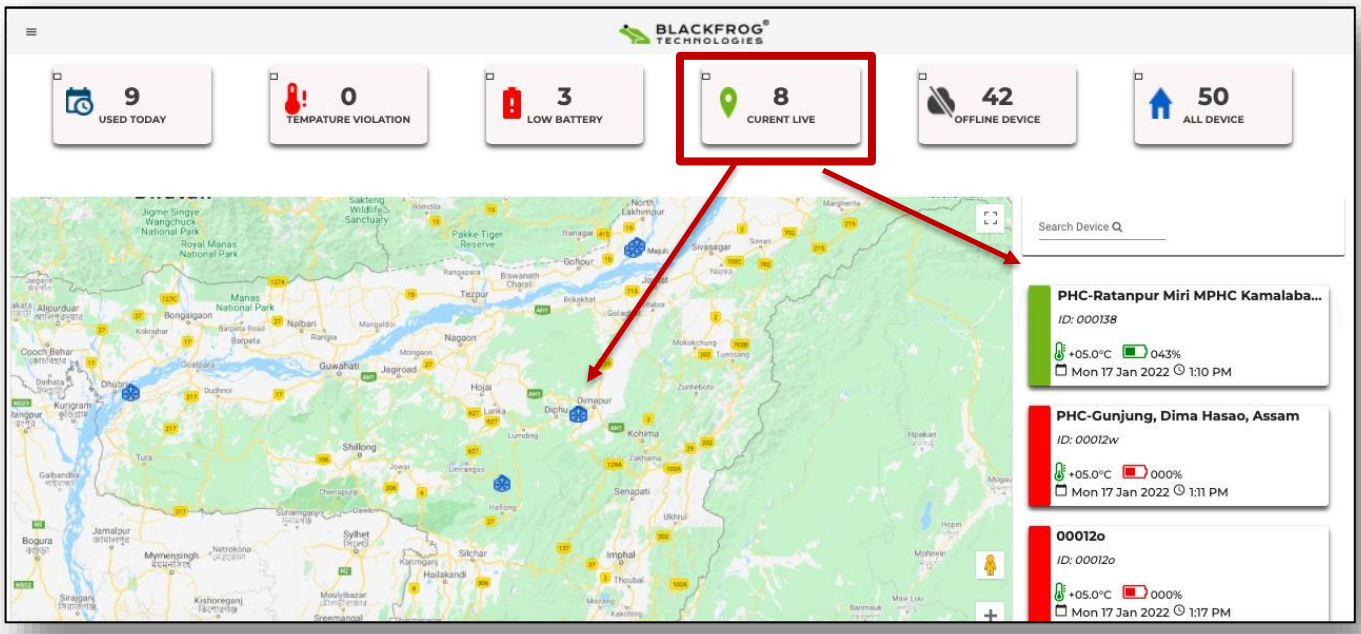
Covaxin 40 doses , Covishield 10 dose
Covaxin 70 doses , Covishield 40 dose
Covishield 20 doses, Covaxin 60 dose
Covishield 60 doses, Covaxin 110 dose
Covishield 70 doses, Covaxin 70 dose
Covishield 50 doses , Covaxin 80 dose
Covishield 60 doses, Covaxin 240 dose
Covishield 80 doses , Covaxin 270 dos
Covishield 30 doses , Covaxin 270 dos
Covishield 50 doses , Covaxin 100 dos
Covishield 80 doses , Covaxin 140 dose
Covishield 70 doses ; Covaxin 60 dose
Covishield 60 doses ; Covaxin 40 dose
Covishield 10 doses ; Covaxin 20 dose
Covishield 50 doses ; Covaxin 80 dose
Covishield 30 doses ; Covaxin 90 dos
Covishield 60 doses ; Covaxin 160 dos
Covishield 10 doses ; Covaxin 80 dos

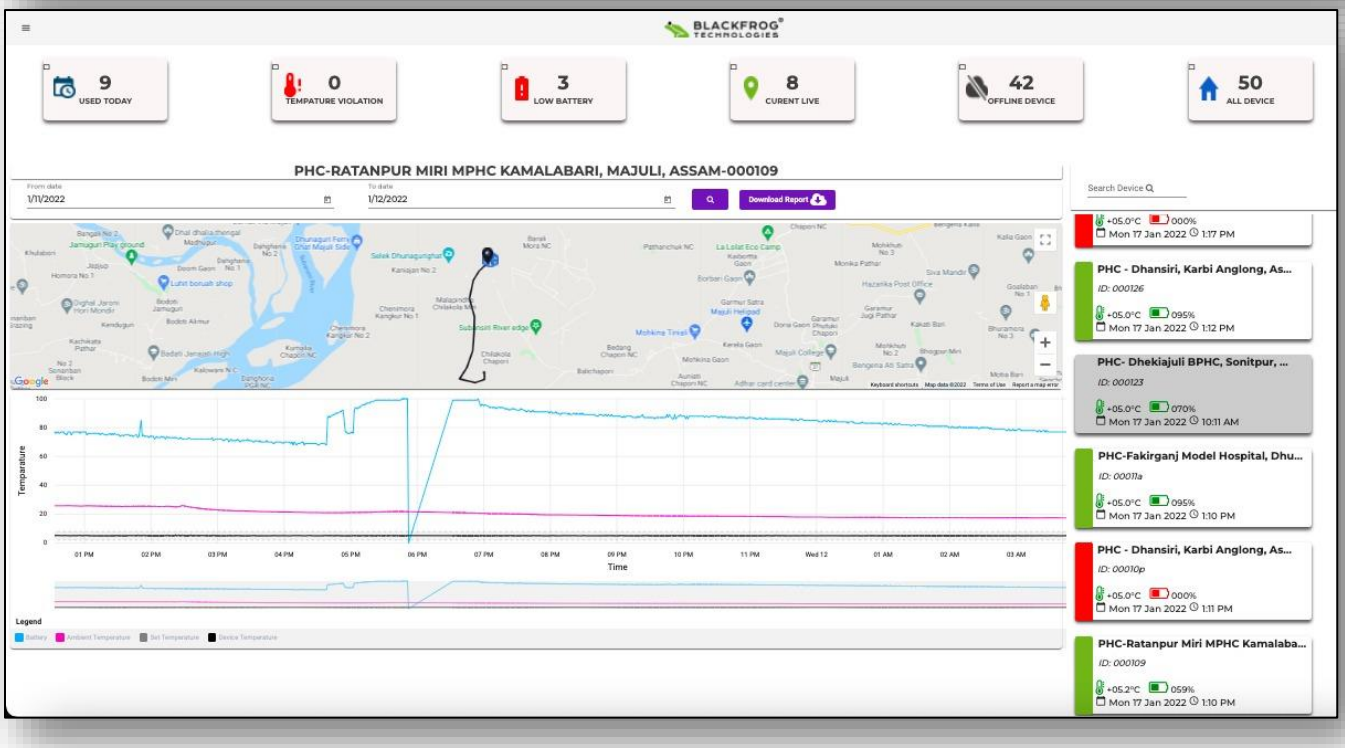
Questionnaire	Medartary, Dhubri
Any challenges faced by you in understanding the usage of Emvolio?	No
Any feedback on using Emvolio (weight, usage, etc)	Used in SD itself. Unable to use Emvolio in field due to weight
What are main issues/challenges usually faced in the field during your duty?	Poor road conditions/backward area/No cars can access, in case of emergency, patients are brought on pull-carts (thela)
What is your experience with this new vaccine carrier ? Has it reduced work hours ? Has it helped in areas where transport & electricity is an issue - if yes, how has it been helpful?	Helpful especially in areas where electricity supply is poor like Medartary SD itself. Device can be taken to residence for charging as well as storage purposes. In summers especially, ice melts, so Emvolio will be suitable as a refrigerator
How many hours of electricity usually available at PHC/sub-centre?	No electricity. Device charged at ANM's residence
Who bears transport cost from 1) PHC to sub-centre 2) Sub-centre to outreach/community centre	AVD payments from DHS(FW) / Ashakarmi from State
Does someone bring the vaccine vials to the PHSC or do you have to carry Emvolio to the storage facility to collect the vaccines ?	AVD brings vials to SD
Have you used Emvolio as a refrigerator when you could not take the vaccines back to the storage unit?	No. But, ANM enquired if this is possible. Has been informed duly that it could be used for refrigeration purposes.
Are you able to trust Emvolio for use in the field ?	Yes, it will be reliable but has not been used yet in the field

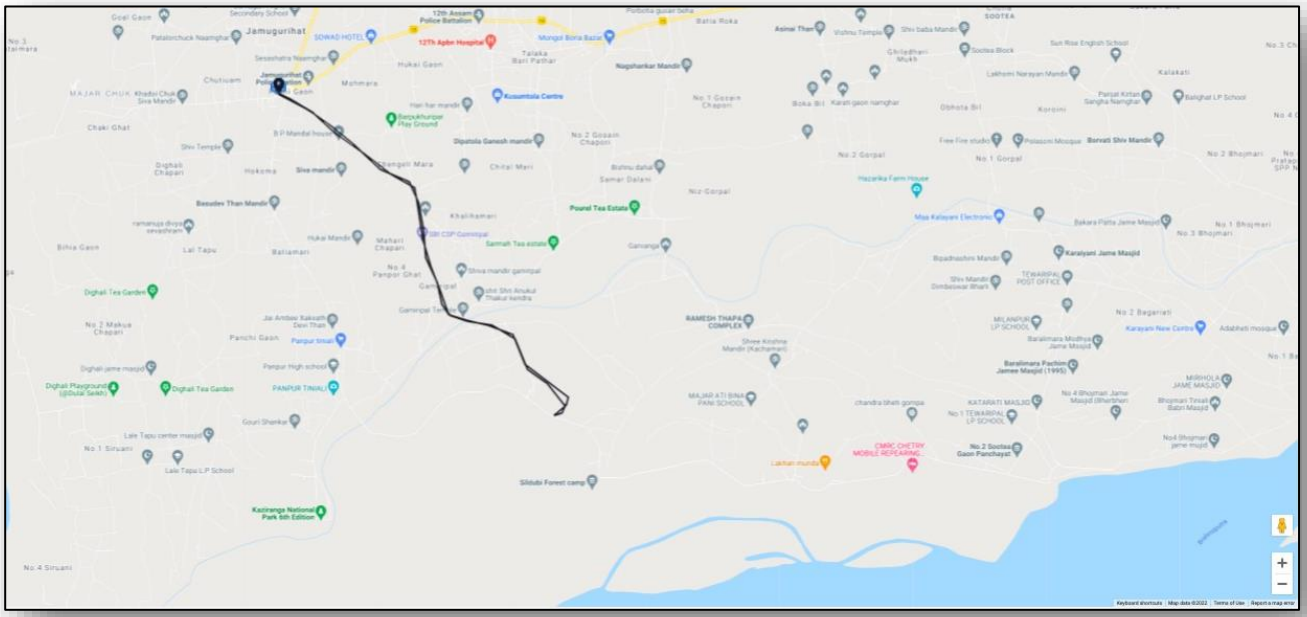
Device Monitoring

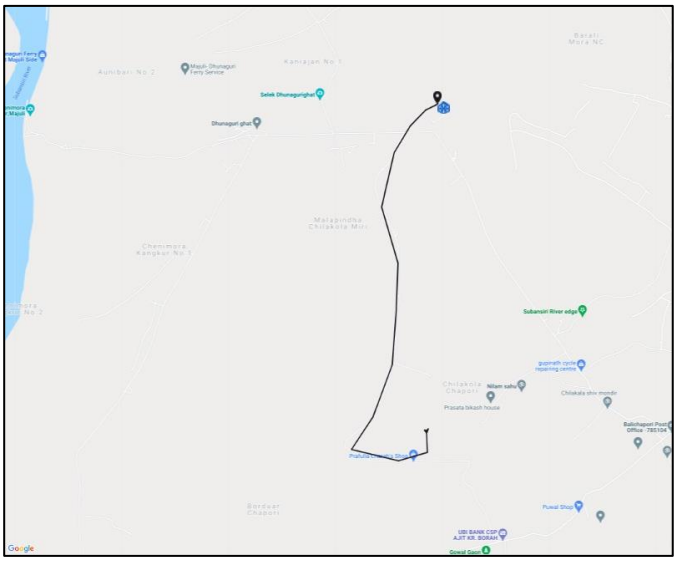
The MyEmvolio Software Platform

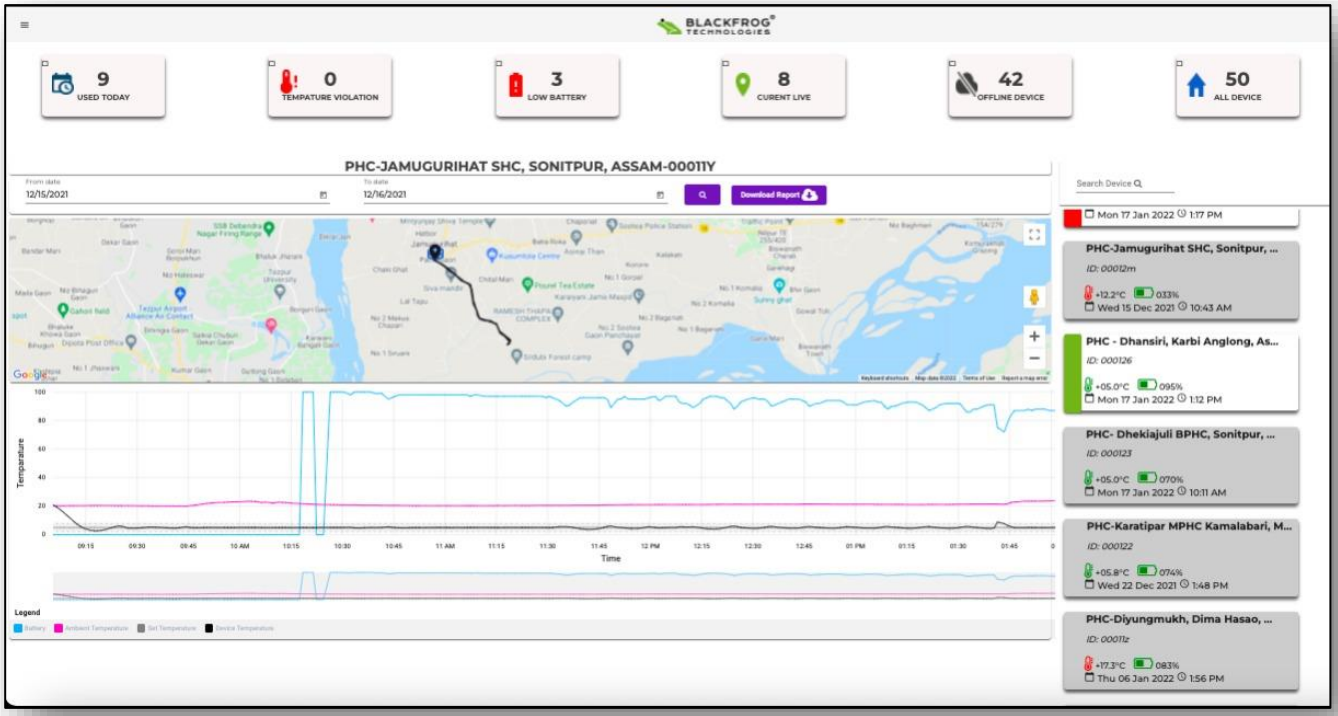
Emvolio vaccine carrier's key feature is the MyEmvolio supporting software for the IoT-enabled live location tracking and monitoring of temperature and battery statistics. This was demonstrated to the office of DHSFW, Guwahati, to enable remote monitoring and view device usage per device per district in real time, especially useful during outreach sessions.

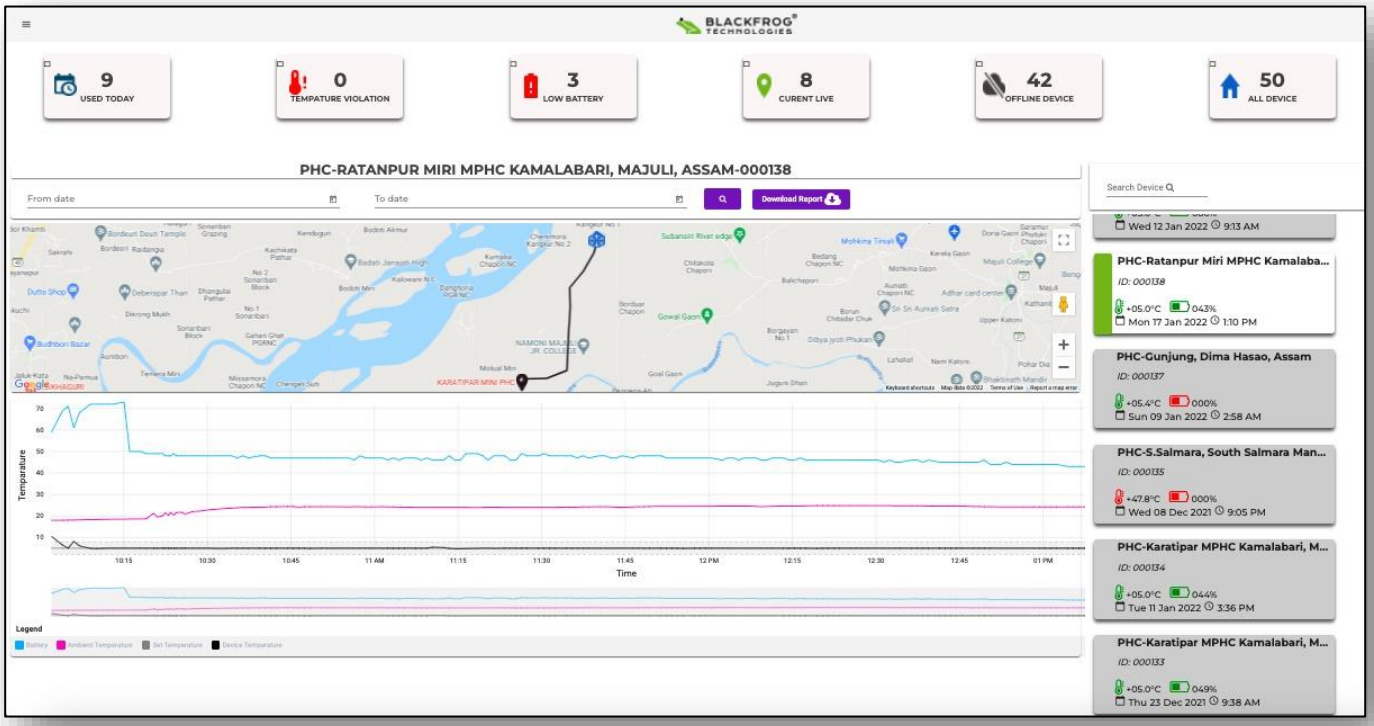












Outcomes | A snapshot

Field Deployment of Indigenous Technology

Through CCAMP's incubation and acceleration platform, an indigenous innovation for last-mile cold-chain (Blackfrog's Emvolio) was selected for rapid deployment in the public health sector.

Blackfrog was selected based on their in-depth understanding of last-mile cold chain challenges in India

Relevance of Technologies Beyond the Pandemic

"Helpful especially in areas where electricity supply is poor like Medartary SD itself. Device can be taken to residence for charging as well as storage purposes. In summers especially, ice melts, so Emvolio will be suitable as a refrigerator."

- *ANM, Medartary S/C, Dhubri*

Scaling of operations from COVID-19 to Maternal & Childcare Programmes, biological samples and storage options in the field

Dissemination of impact for technology scale-up and highlighting the catalysing role of DHSFW & HTPF

In working with DHSFW & HTPF, the teams have learned about additional areas of support needed and have begun working on solutions for the same.

This includes collaboration for solar-enabled PHCs, improvement in remote monitoring through dashboard, inventory support, upgradation of backpacks for better weight distribution, revision of training protocol to address WHO standards.

Context relevant technology development	Feedback from the Assam deployment has helped with improving Blackfrog's next-generation cold-chain product and scaled R&D efforts to meet requirements on the ground. These efforts are being aligned directly to the needs of ANMs, CCHs, and other healthcare workers in public settings on the ground.	
Bringing indigenous technology and innovation to cold-chain practices	The site monitoring and beneficiary interviews show that there are challenges in adoption of an active carrier viz-a-vis the existing passive carriers. Behaviour modification is favoured by time and at the end of 3 months, there is a positive outlook towards acceptance of indigenous technology being fostered. This will help with the integration of new technologies in the public health sector in the future. The benefits and generation of real-world last-mile cold-chain data will help with further integration and adoption into the Indian healthcare system.	

Case Study

By C-CAMP Technology Impact Programme

Understanding the Cold-Chain System for the development of an Immunization & Vaccination Model for Improved Healthcare

> *Vaccines—and lives—at risk Approximately 70 percent of the vaccines procured annually by UNICEF are freeze-sensitive, totaling $70 million per year. Exposure of these freeze sensitive vaccines to extreme cold could result in a staggering loss of money and effort, and leave vaccinated patients unprotected from vaccine-preventable diseases.*

PATH, WHO. Above Zero: Strategies to Prevent Vaccine Freezing. Seattle: PATH, WHO; 2013.

According to Ministry of Health and Family Welfare (MOHFW) India, Vaccine Management has an objective to maintain the safety and potency of vaccine during storage and transportation. The vaccines lose their potency if they are not stored or transported at the recommended temperature and condition. If vaccines are not stored safely (within recommended temp.), it may lead to Adverse Event Following Immunization (AEFI). Hence all attempts should be made to retain the safety of the vaccine, and maintaining the recommended temperature.

Checking for heat damage: The Vaccine Vial Monitor (VVM) is a label containing heat-sensitive material, which is placed on the vaccine vial to register cumulative heat exposure between the time period of exit from the manufacturing site till the time of use. The combined effects of time and temperature causes the inner square of the VVM to darken gradually and irreversibly. Before opening a vial, check the status of the VVM. Does a VVM measure vaccine potency? No, the VVM does not directly measure vaccine potency but it gives information about a major factor that affects potency, i.e., heat exposure over a period of time. The VVM does not, however, measure exposure to freezing that contributes to the degradation of freeze-sensitive vaccines

Freeze Damage: 1. Causes of freezing a. Improper storage in Ice lined refrigerator: b. Cold climates and ambient temperature is less than 0°C c. Storage and transport with non-conditioned frozen ice packs. d. Defective ILR. e. Untrained or improperly trained staff handling vaccine/cold chain. f. Incorrect thermostat adjustment (Handbook for Vaccine & Cold Chain Handlers, 2nd edition, India, 2016).

The development and introduction of a unique solution in cold-chain to address the above challenges and concerns in the field has been undertaken by many organisations and academic institutes over the decade. However, very few have been successful in building a solution that has the overarching aim of reducing as many potential problems in the field such as –

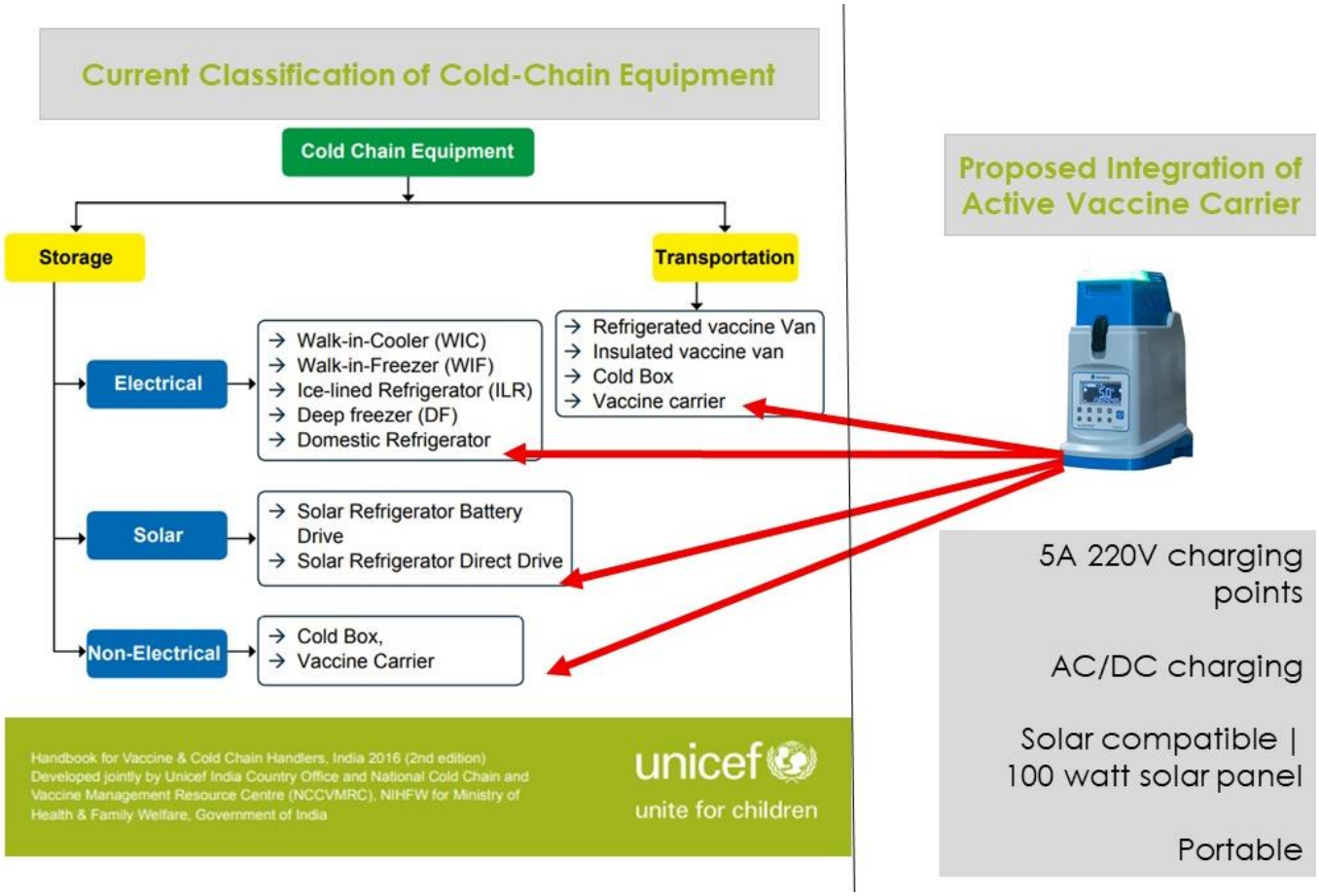
- Poor or no electrical supply
- Strict temperatures of 2 to 8 °C across drastic ambient temperatures
- Portability in difficult terrains
- Weatherproofing to meet the diverse climate across Indian regions
- Difficulty in end-user training and capacity building
- Efficient management through IoT -based technology
- Temperature monitoring without data loggers,
- Scaled-down routine and operating protocol for maintenance of vaccine carriers
- Capacity for multiple types of biological samples and specimens

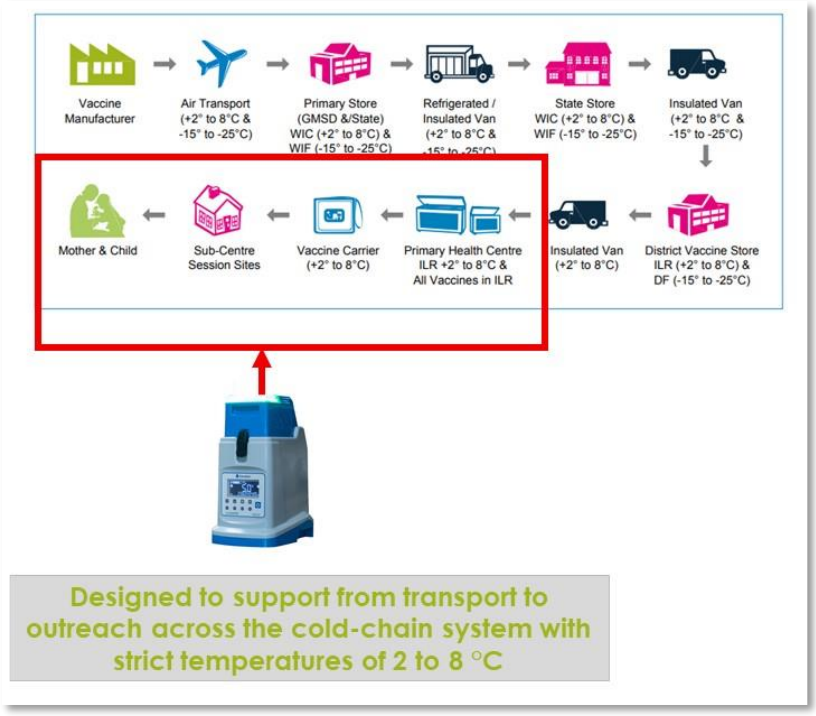
The Emvolio Active Vaccine Carrier is one such technology that does so. The current scenario surrounding the COVID-19 pandemic has resulted in the rapid scale of technological solutions to address the growing needs. Under the above circumstances, C-CAMP, introduced Blackfrog Technologies to the State of Assam and Manipur with a deployment of 100 active vaccine carriers over a period of 6 months.

There have been challenges in deployment and adoption of a new disruptive technology in the last-mile process for the safe transportation and delivery of both COVID-19 vaccines and routine immunization vials. New ministry-approved protocols need to be developed for India to scale and grow in its vaccination and immunization efforts. Adoption of any new technology varies across cultures and communities based on multiple factors. Healthcare is a highly regulated field that requires behaviour modification practices to move the needle towards better health outcomes. This can be enabled through understanding, education and collaborative efforts across stakeholders in the public and private healthcare sectors. This is C-CAMP's goal, to provide access and affordable technology through its expertise to develop models for improved healthcare practices and standards.

The current deployment can generate evidence d can support proposals at a policy level for cold chain technology, there is a changing trend towards the recommendation and use of active portable refrigeration carriers for all vaccinations versus passive carriers. This recommendation for cold-chain technology is done globally by WHO, whose standards for are followed in India by the Ministry of Health. There is a strong focus on PQS product specifications for portable, active vaccine carriers over passive carriers. (WHO Performance, Quality and Safety (PQS) process prequalifies products and devices so that member states and UN purchasing agencies are assured of their suitability for use in immunization programs.) **Emvolio is designed as per WHO PQS standards and will be applicable for prequalification by February 2022 when the World Health Organisation commences prequalification applications.**

Comparing current protocols and SOPs with Emvolio Active Vaccine practices





Uses: To carry vaccine from last CCP to outreach sessions and bring back the open vials (Under the Open Vial Policy) from the session sites for storing & subsequent use.

How to pack a vaccine carrier

- → Confirm that there are no cracks in the walls of the vaccine carrier.
- → Take out the required number of ice packs from the deep freezer and wipe them dry. Keep them out side for conditioning before placing into carrier.
- → Place four conditioned ice packs into the vaccine carrier along the sides.
- → Wrap vaccine vials and ampoules in thick paper (e.g. plain white paper) before putting in polythene bag so as to prevent them from touching the ice packs. This would also help in absorbing the moisture as accumulation of moisture would damage the labels on the vaccine vials.
- → Place the plastic bag in the centre away from the ice packs. This will prevent labels from peeling off from the vials.
- → Place foam pad on top of ice packs
- → If more than one vaccine carrier is being carried for a single session site, keep the whole range of the vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

Some useful Do's and Don'ts:

- → Ensure that some ice is present in the ice packs while conducting immunization sessions.
- → Ensure collection of vaccines in the vaccine carrier on the session day only.
- → Avoid dropping, knocking or sitting on the Vaccine Carrier.
- → Do not leave the vaccine carrier in the sunlight.
- → Close the lid tight & securely.

Handbook for Vaccine & Cold Chain Handlers, India 2016 (2nd edition)
Developed jointly by Unicef India Country Office and National Cold Chain and Vaccine Management Resource Centre (NCCVMRC), NIHFW for Ministry of Health & Family Welfare, Government of India

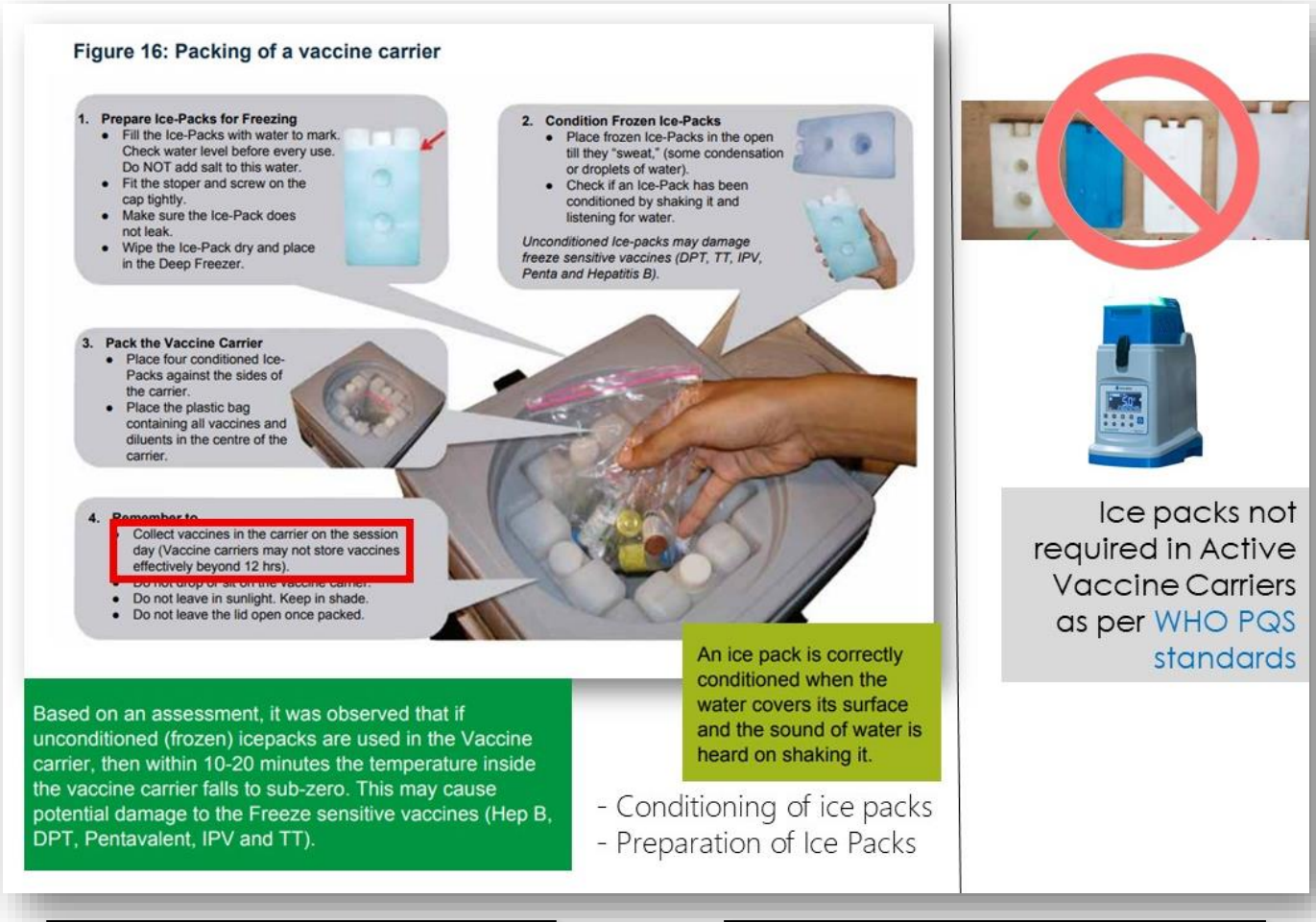
unicef
unite for children

1. Switch on Emvolio Active Vaccine Carrier – to begin active cooling
2. Wait for LED indicator on device to turn GREEN
3. Collect vaccine vials and place vials in a plastic zip lock pouch carefully
4. Unlock the lid of Emvolio Active Vaccine Carrier
5. Place the zip lock pouch containing the vials inside the cooled chamber
6. Close the lid and lock before carrying

NOTE: Lid can remain unlocked during immunisation sessions, easy to open and close without compromising temperature inside

Device can be kept in direct sunlight

Do Not Obstruct / Block the lid or vent at the top of the device



Primary responsibility of vaccine and cold chain handler

1. Daily maintenance and cleanliness of cold chain equipment
2. Daily temperature recording
3. Monthly vaccine and logistics indent, receipt and storage
4. Timely issue of vaccine to the lower store/sessions as per microplan
5. Timely update of stock and issue registers for vaccines and logistics
6. Breakdown reporting
7. Monthly vaccine utilization including wastage reporting

The damaged vaccines must be discarded and disposed off as per the Immunization Waste Disposal Guidelines. It may lead to inadequate vaccine stock and blockage of storage space. Moreover, children and women who receive a vaccine that is not potent, are not protected adequately.

Can Emvolio Active Vaccine Carrier improve vaccine management through temperature monitoring real-time display?

Vaccine Management has an objective to maintain the safety and potency of vaccine during storage and transportation. The vaccines lose their potency if they are not stored or transported at the recommended temperature and condition. If vaccines are not stored safely (within recommended temp.), it may lead to Adverse Event Following Immunization (AEFI). Hence all attempts should be made to retain the safety of the vaccine, and maintaining the recommended temperature.

Heat (Temp above +8°C) – all vaccines under UIP

Cold (Temperature below + 2°C) – Hep. B, Pentavalent, IPV, DPT and TT

Light – BCG and Measles

> Bull World Health Organ. 2013 Dec 1;91(12):906-13. doi: 10.2471/BLT.13.119974. Epub 2013 Sep 9.

Frequent exposure to suboptimal temperatures in vaccine cold-chain system in India: results of temperature monitoring in 10 states

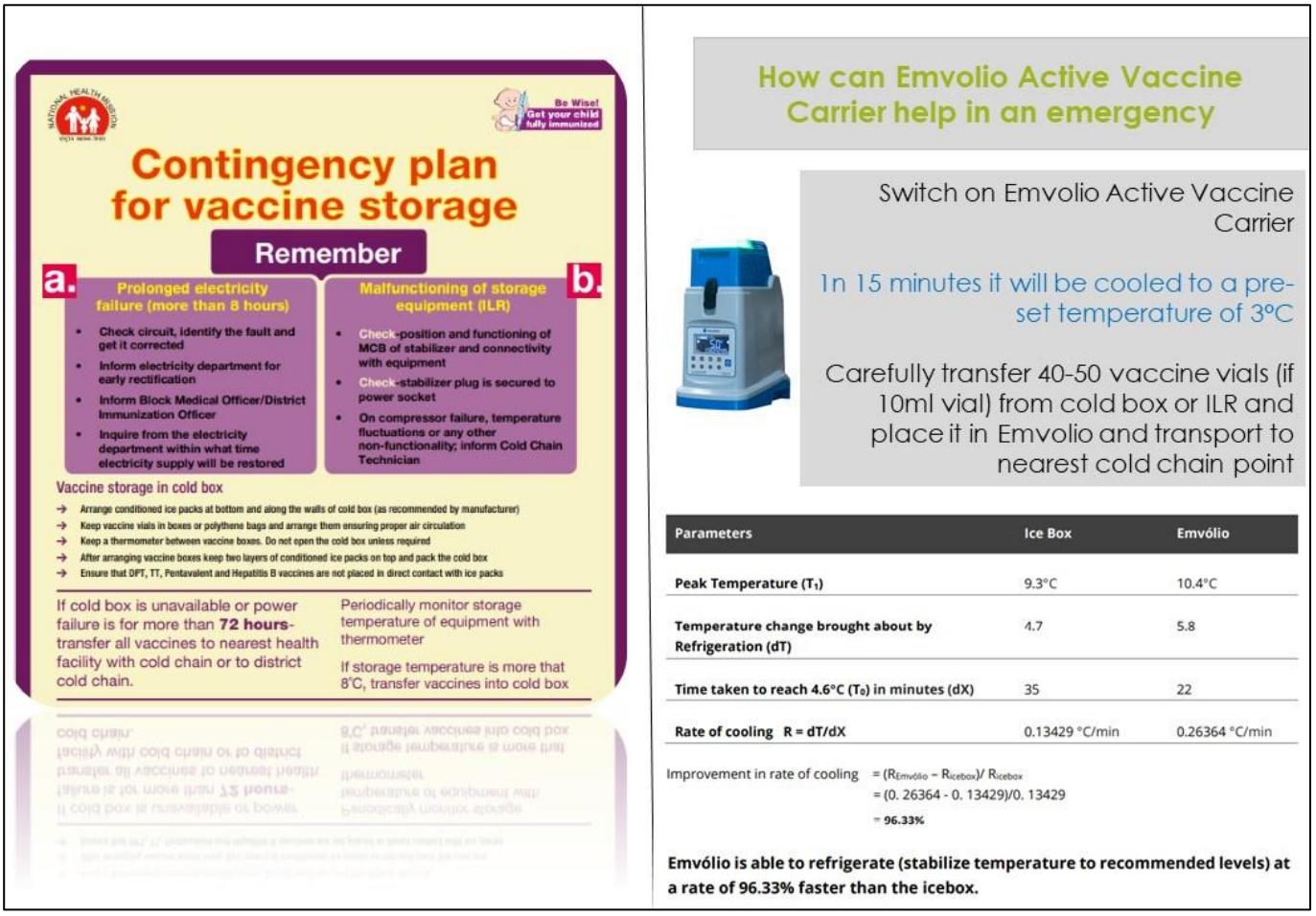
Manoj V Murhekar [1], Srihari Dutta [2], Ambujam Nair Kapoor [3], Sailaja Bitragunta [4], Raja Dodum [5], Pramit Ghosh [6], Karumanagounder Kolanda Swamy [7], Kalyanranjan Mukhopadhyay [8], Somorjit Ningombam [9], Kamlesh Parmar [10], Devegowda Ravishankar [11], Balraj Singh [12], Varsha Singh [13], Rajesh Sisodiya [14], Ramaratnam Subramanian [7], Tana Takum [5]

Affiliations + expand

PMID: 24347729 PMCID: PMC3845272 DOI: 10.2471/BLT.13.119974

Findings: In state, regional and district vaccine stores and peripheral health facilities, respectively, the temperatures in the boxes exceeded 8 °C for 14.3%, 13.2%, 8.3% and 14.7% of their combined storage times and fell below 0 °C for 1.5%, 0.2%, 0.6% and 10.5% of these times. The boxes also spent about 18% and 7% of their combined times in transit at < 0 and > 8 °C, respectively. In shake tests conducted at the end of the study, two thirds of the vaccine vials in the boxes showed evidence of freezing.

Conclusion: While exposure to temperatures above 8 °C occurred at every level of vaccine storage, exposure to subzero temperatures was only frequent during vaccine storage at peripheral facilities and vaccine transportation. Systematic efforts are needed to improve temperature monitoring in the cold-chain system in India.



Contingency plan for vaccine storage

Remember

a. Prolonged electricity failure (more than 8 hours)

- Check circuit, identify the fault and get it corrected
- Inform electricity department for early rectification
- Inform Block Medical Officer/District Immunization Officer
- Inquire from the electricity department within what time electricity supply will be restored

b. Malfunctioning of storage equipment (ILR)

- Check-position and functioning of MCB of stabilizer and connectivity with equipment
- Check-stabilizer plug is secured to power socket
- On compressor failure, temperature fluctuations or any other non-functionality; inform Cold Chain Technician

Vaccine storage in cold box

- Arrange conditioned ice packs at bottom and along the walls of cold box (as recommended by manufacturer)
- Keep vaccine vials in boxes or polythene bags and arrange them ensuring proper air circulation
- Keep a thermometer between vaccine boxes. Do not open the cold box unless required
- After arranging vaccine boxes keep two layers of conditioned ice packs on top and pack the cold box
- Ensure that DPT, TT, Pentavalent and Hepatitis B vaccines are not placed in direct contact with ice packs

If cold box is unavailable or power failure is for more than **72 hours**- transfer all vaccines to nearest health facility with cold chain or to district cold chain.

Periodically monitor storage temperature of equipment with thermometer

If storage temperature is more that 8°C, transfer vaccines into cold box

How can Emvolio Active Vaccine Carrier help in an emergency

Switch on Emvolio Active Vaccine Carrier

In 15 minutes it will be cooled to a pre-set temperature of 3°C

Carefully transfer 40-50 vaccine vials (if 10ml vial) from cold box or ILR and place it in Emvolio and transport to nearest cold chain point

Parameters	Ice Box	Emvólio
Peak Temperature (T_1)	9.3°C	10.4°C
Temperature change brought about by Refrigeration (dT)	4.7	5.8
Time taken to reach 4.6°C (T_0) in minutes (dX)	35	22
Rate of cooling R = dT/dX	0.13429 °C/min	0.26364 °C/min

Improvement in rate of cooling $= (R_{Emvólio} - R_{icebox})/ R_{icebox}$
$= (0.\ 26364 - 0.\ 13429)/0.\ 13429$
$= 96.33\%$

Emvólio is able to refrigerate (stabilize temperature to recommended levels) at a rate of 96.33% faster than the icebox.

Phase 2 | To develop a comprehensive protocol for Emvolio active carriers for use in immunisation and vaccination activities, based on gap analysis and technology feedback from Assam, to meet the goal of reducing vaccine wastage and improving health outcomes