**Biotechnology Industry Research Assistance Council**

**(BIRAC)**

**A Government of India Enterprise**

# Request for Proposal (RFP)

Grand Challenges India Funding Opportunity

for the

## "Immunization Data: Innovating for Action (IDIA)"

call

Jointly funded by

**Department of Biotechnology (DBT)**

**Ministry of Science and Technology**

**Government of India**

**&**

**Bill & Melinda Gates Foundation (BMGF)**

## 1. Introduction

### Grand Challenges India

In 2012, the Department of Biotechnology, Government of India, and the Bill & Melinda Gates Foundation signed a Memorandum of Understanding (MoU), where both parties agreed to collaborate on scientific and technological research to alleviate some of the world's most critical global health and development issues, for the benefit of the people of India and other developing countries.

This partnership seeks to identify opportunities to initiate and promote scientific and technological research in the country, to provide India-specific solutions for the country, which can then be adapted for use in other developing countries. Specifically, the partnership focuses on encouraging research and exploring avenues to reduce maternal and child mortality and morbidity; developing scientific and technical solutions for infectious diseases; strengthening India's scientific translation capacity; developing scientific and technical advances related to agriculture, food and nutrition, among others

Grand Challenges initiatives follow these core principles:

1. Strategic and well-articulated grand challenges serve both to focus research efforts and capture the imagination and engage the world's best researchers.
2. Projects are selected based on national and societal need and transparent calls for proposals seeking the best ideas.
3. Funders, investigators and other stakeholders actively collaborate to accelerate progress and integrate advances to ensure these advanced technologies reach to developing countries masses
4. Projects are selected not only for scientific excellence, but also for their likelihood to achieve the desired impact, and they are milestone-driven and actively managed to that end.
5. Projects and investigators will have to follow global access commitments to ensure the fruits of their research are available to those most in need.

Here we announce a call titled '**Immunization Data: Innovating for Action (IDIA)**', a program directed at addressing challenges that we face in collecting, analyzing and using data on immunization and health in technical partnership with the Ministry of Health and Family Welfare, Government of India, the Department of Health Research (DHR) and the Indian Council of Medical Research (ICMR), who will be providing their valuable technical and practical inputs in selecting and reviewing projects.

This Request for Proposals (RFP) is specific to India and open to anyone who is interested in applying – including academics, research institutions, medical research institutions, for-profit companies, not-for-profit organizations, and foundations.

Grants will be to researchers and innovators who are Indian individual or Indian entities[1], but we encourage partnerships with researchers in other countries, especially where the opportunity exists to build on established collaborations.

## 2. Program Details

The overall goal of the program is to conceptualize and demonstrate innovations in data systems for immunization to aid in real-time visibility of correlation between consumption and coverage of immunizations.

### a. Background

The advancement in immunizations since the last century has led to hitherto unprecedented improvements in health outcomes across the globe. Vaccination has led to two diseases, smallpox and rinderpest, being eradicated, and another disease, polio, being in the last stages

[1] *An Individual should be a Citizen of India
*Indian entities are defined as those established under any relevant statute, agreement, rule or regulation in India.

of eradication. Immunization has contributed immensely to reductions in mortality for vaccine preventable diseases and has substantially reduced morbidity[2].

The bedrock of immunization efforts is accurate, timely and accessible data. Immunization data covers a wide range of indicators, from coverage to consumption, each of which, individually and in combination, give us important information on the reach, effectiveness and the gaps in immunization programs. Appropriately utilized data informs on management and performance of these programs. Accurate data also helps us understand the disease burden of the country and helps us develop and implement policies and programs to address these shortfalls. Data on immunizations that is clear, reliable and real-time will in the long-term help protect the investment that the country makes in implementing the Universal Immunization Program and to ensure that the taxpayers' funds are used in the most efficient manner to deliver the positive impact that it is meant to.

India has made immense strides in the field of immunization. Today, the country's Universal Immunization Programme (UIP) is the largest in the world in terms of the quantities of vaccines administered, number of beneficiaries, number of immunization sessions, and geographical extent and diversity of areas covered[3]. Through concerted efforts of the government and international donors, the country was declared polio-free in 2014, through one of the largest mass immunization campaigns. India has introduced 5 new vaccines (IPV, adult JE, Rota, PCV, MR) in last three years. Under the visionary leadership of our Honorable Prime Minister, the country has also launched Intensified Mission Indradhanush programme to reach the vulnerable last mile who are children with this expanded basket of vaccines. Through the earlier phases of Mission Indradhanush, India reached 68 lakh pregnant women and 254 lakh children registering an unprecedented 6.7% annual increase in coverage.

This rapid pace of the universal immunization programme requires reliable, timely and advanced measurements to further guide its progress.

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[2] Vashishtha VM and Kumar P., 2013, 50 years of Immunization in India: Progress and future, Indian Pediatrics, 50,111-118.

[3] Chatterjee S., Pant M et al., 2016, Current costs & projected financial needs of India's Universal Immunization Programme, Indian J Med Res 143, 801-808.

The country collects data on immunization through a variety of methods such as through administrative data, registry-based data and census data, among others. There has also been an evolution in the way that we record and report on immunization services: through the migration of immunization data from a stand-alone system to more integrated health data systems, as evidenced from modification of UIP card to Mother and Child Protection (MCP) card incorporating broader maternal and child health aspects, mirroring integration of Routine Immunization (RI)days into VHNSD (Village Health, Nutrition and Sanitation Days); the development of electronic data system on the foundation of the pen and paper based reporting, as noted in the genesis of Health Management Information System (HMIS) and the development of name-based data registry through Mother and Child Tracking System (MCTS), further maturing into RCH data portal.

Similarly, the monitoring and evaluation of immunization services has come of age through proliferation of various surveys, partner-initiated field monitoring and some scattered operation research. The disease surveillance has mostly been initiated and led by the Integrated Disease Surveillance Programme (IDSP), National Polio Surveillance Project (NPSP) and the Indian Council of Medical Research (ICMR).

For further details on the existing immunization data systems in the country, please refer to Annexure 1*.

However, each method has its own challenges in implementation and additionally differences in methodologies and mismatches between the numbers from different methods demands innovative solutions that can give validated data to the policymakers, programme managers and healthcare workers in real time an accurate picture of the immunization landscape across the country. The country has also taken strides in digitizing its entire vaccine supply chain data through such innovative approaches like eVIN (electronic vaccine intelligence network) and the frontline service data through solutions like ANMOL (ANM online).

In tune of these innovations already brought into the programme and in alignment of the new digital India, this grand challenge aims to further strengthen the data systems in order to build up a 21st century vaccination services in the country. The draft national Monitoring and Evaluation (M&E) plan for immunization points also out that "*despite being large and resource intensive, the Immunisation Programme in India has limited focus on monitoring and evaluation. There are many challenges in the current M&E system for health. Most of these challenges are due to non-standardization of the reporting system, fragmented monitoring, disconnect between M&E and planning functions, low capacity to manage M&E system and quality issues*". The Comprehensive Multi Year Plan for Immunization (cMYP) 2013-17 also recognises that though there are provisions for immunization program reviews, these are not regular and are not effective in the absence of a real-time quality data and the convergence among multiple systems is sub-optimal.

The data landscape today faces many challenges across the board, in collection, analysis and use.

**A. Data collection**

a. The reported data visibly suffers from poor timeliness, incompleteness and inconsistencies
b. There is both numerator (missing or delayed entries and variables) and denominator problems (ill-defined catchment area, missing urban data)
c. There is almost irreconcilable differences between reported and evaluated data and between two sources of reported data (HMIS and MCTS)
d. There are other data systems within immunization in different stages of maturity- which do not talk to coverage data
e. The surveillance system is fragmented with lab-supported component for Acute Flaccid Paralysis (AFP) and measles-rubella only. The wider VPD surveillance is in nascent stage.

B. **Data analysis**

a. There is dearth of dynamic dashboards with clear interpretation and guidance

b. The evaluation efforts (National Family Health Surveys, District Level Health Survey, Annual Health Survey, FRDS etc.) vary in their scope, size, methodology and confidence intervals

c. No data system is inter-operable with any other till now

d. There has been no system to reconcile coverage with utilization of vaccines

C. **Data use**

a. State and district task forces for immunization are constituted on the line of polio task forces but the actual periodicity and effectiveness of these task forces are not well monitored

b. Awareness and competence of health officials at all levels to adequately and appropriately use data remain sub-optimal

c. Despite some useful examples of data-driven decisions at the federal level, such efforts are lacking in states and even where some efforts are taken, they are not well documented to be institutionalized as a process

d. No systematic Data Quality Assessment (DQA) is undertaken at scale to improve the quality of data

The immunization data is also challenged by some cross-cutting systemic issues:

- **Accountability and performance management:** Performance of the delivery system is inadequately driven by programmatic data at both individual and collective level.
- **Sustainable human capability:** The training of data people has not got sufficient attention till date. The vacancy and turn-over of key staff compound the problem. The basic skill set to use data for programmatic improvement is widely variable across the functionaries.
- **Horizontal vs. vertical:** As the EPI/ UIP precede RMNCH+A programmes, it provides the base platform to deliver the entire basket of RCH services. Consequently, the data produced by immunization programmes is nested within the broader health data systems and get influenced and complicated by the broader system-demands.

**Fulfilling an unmet need**

There is therefore an unmet need for an immunization data system or a new way of thinking on data collection, analysis and use to harness the potential of the information that we are missing today. Reconciling coverage and consumption data on immunization is crucial to ensuring that we get an accurate picture of the immunization and disease burden landscape. Immunization is also long-term public health intervention in most cases; therefore there is need for a sustainable data collection and analysis system that is robust and dynamic to manage the demands of it in the future.

### b. Programme objective

The Department of Biotechnology, Government of India and the Bill & Melinda Gates Foundation under Grand Challenges India seek proposals that address the challenges in immunization data systems in India that are different from current approaches and stretch the frontiers of the programme. The solutions submitted to this GCI program may deal with integrated health information, or may focus specifically on immunization only. They should have the potential to be scaled up in multiple settings. We also encourage solutions that translate leading and best practices and solutions developed by the private sector as well as academic research, even from outside health sector.

### c. What we are looking for

Proposals must provide a strong rationale for the work proposed, demonstrating a clear understanding of India's context and needs, and present a defined hypothesis and associated plan for how the idea would be tested or validated. Proposed ideas should be potentially translatable to practical interventions in India's immunization programme.

**A few examples of work that would be considered for funding:**

**Tracking and triangulation:**

1. Innovative solution to converge the coverage (ANMOL / CAS) and consumption data (eVIN- electronic Vaccine Intelligence Network) for vaccines
2. Innovative solutions to validate and strengthen immunization delivery microplanning and mapping efforts, including but not restricted to GIS solutions

3. Novel approach to track coverage of the migrant and mobile populations including pastoral groups
4. New solutions to integrate data from the immunization delivered in the private sector
5. New technologies to use UID (AADHAR), biometry etc. for beneficiary registration and home-based- records
6. Tracking individual vaccine vials within a hierarchical supply chain system
7. Easy yet effective session reminder system for the beneficiaries
8. Tool for the beneficiaries to find out the availability of sessions, services and their status
9. Innovative approach to effectively scan and use social media for more effective communications

**Analytics and quality:**

10. New tools to produce dynamic visualization with analytics by triangulating different data systems (HMIS/ MCTS/ Surveys/ Monitoring) on a single platform
11. Innovative methods to conduct rapid, low cost, granular coverage surveys for immunization
12. Innovative solutions for data quality diagnosis at all levels
13. Using BIG data analytics to generate relevant signals on different aspects of vaccination programme performance

**Capacity and accountability**:

14. New approaches to improve immunization data literacy and user capacity across all levels
15. New approaches to incentivize data transparency, sharing and use
16. Novel solutions to link immunization data to programme and personnel performance management

d. **What we are <u>not</u> looking for**

1. Proposals that do not directly address at least one of the challenges described above;
2. Proposals without a clearly-articulated objective or an objective that cannot be easily assessed for quality, efficiency and/or effectiveness;

3. Proposals addressing preclinical or clinical research, surveillance for vaccine preventable diseases, sero surveys, conventional coverage or demographic health surveys;
4. Approaches that represent incremental improvements to current activities or conventional solutions, or iterative/duplicative solutions;
5. Approaches that are not applicable in India;
6. Approaches for which proof of concept cannot be demonstrated within the funding levels described for this call;
7. Proposals that do not describe or outline the innovation's effects in the context of the broader health and routine immunization system;
8. Proposals that can only be applied to individual manufacturers' products or specific product improvement initiatives.

## e. Program Structure

### i. Funding pattern

**Phase I - Grant for developing proof of concept (12-18 months)**: Funded at up to $200,000 USD each project, these awards require preliminary data and are meant to provide an opportunity to develop, refine, and rigorously test approaches that have previously shown promise in controlled or limited settings.

**Phase II** - **Grant for validating impact (18-24 months)**: This grant is envisaged for follow funding to scale the most successful and impactful projects from Phase I, with the ultimate aim being integration into the government program.

### ii. Collaboration

GCI encourages collaborations based on the belief that synergies between experts across diverse disciplines are important for the challenges that we seek to address.

Should you want to apply as a collaboration, please ensure the following questions are sufficiently answered in you proposal.

Are the applicants, including all sub-contractors, willing to collaborate and share experimental methods, data, and resources among the other independently funded members of the program consortium?

## 3. Rules and Guidelines

### a. Application Process

**i.** Proposals in the correct format will be submitted on the online portal by interested applicants

**ii.** After an initial triage, review panels established under the Grand Challenges India partnership will evaluate the full proposals submitted.

**iii.** Post full proposal review, the applicants will be invited to present their proposals in detail to TAG.

**iv.** Pending financial and technical due diligence, the final awardees will be selected by the TAG.

**v.** Once Due Diligence is successfully completed, award certificates will be awarded to the selected GCI applicants.

**vi.** PMU- BIRAC will then enter into separate funding agreements with successful GCI grantee(s) to govern the project terms and conditions and fund disbursement modalities.

### b. Application instructions*

1. Please visit the BIRAC website at www.birac.nic.in and follow the link to the registration and submission portal.
2. The online form needs to be filled completely with all appropriate documents uploaded.
3. Please also ensure that the Proposal Summary document is uploaded based on the format provided. Incomplete proposals will be rejected in the triage round.

* We will not be able to provide individual feedback to applicants those who are not selected for further rounds.

### c. Schedule

November 15, 2017: Launch of RFP

January 15, 2018: Call closes. The portal will close for submissions at midnight.

August 2018: Award Announcement

### d. Eligibility criteria

This RFA is India-led; the programme is open to academics, research institutions, medical research institutions, for-profit companies, not-for-profit organizations, trusts and foundations.

Grants will be made to researchers and innovators who are Indian individual or Indian entities*****, we also encourage partnerships with researchers of national/international expertise.

Experts of the relevant discipline as mentors should be a part of the proposal such as healthcare professionals, data analytics experts, mhealth specialists, management experts, logistics experts, immunizations specialists, M&E experts and market analyst among others.

Through national and international collaboration, we expect that sharing experimental methods, data, and resources will ultimately improve the ability to compare and validate local research findings and to develop interventions and products that can have impact at a greater scale.

### e. Evaluation Criteria

1. **Novelty and Innovation [20]:** Does the proposal capture enough novelty to address the challenges immunization data systems.

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- * An Individual should be a Citizen of India

  Indian entities are defined as those established under any relevant statute, agreement, rule or regulation in India, company and LLP should have at least 51% of resident Indian shareholder/ subscriber.

2. **Approach and methodology [20]:** Is the research plan, objective and proposed schedule clearly presented and realistic. Is there clarity in the objectives and work plan? Are the proposed timelines and milestones appropriate, feasible, and technically sound? Is there a high likelihood of the objectives being completed in the given timeframe? Will the demonstration take place in difficult/ challenging India-centric programme setting?

3. **Future Deliverable/Translational Feasibility [20]:** Relevance and clarity of anticipated outcomes & deliverables to future implementation of the projects and commercialization.

4. **Sustainability and adaptability of System [15]**: Does the approach demonstrate inter-operability with the current health system of the country. Does the proposed solution take into account the complexity of the proposed geographical setting and context

5. **Organizational and investigator capability [15]:** Is the team composition covering key scientific and engineering challenges that this challenge is seeking to address? Is the research and development team appropriately trained, experienced, and positioned to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other proposed members? Is there strong evidence of substantive organizational capability and commitment? Is there experience in development of partnerships, and in multi-investigator projects? Are collaborative arrangements in place? Is there evidence of an infrastructure for data collection, transfer, and sharing?

6. **Best value [10]:** Is the cost of the proposed effort reasonable relative to the complexity of the proposed work and the degree of risk and advancement proposed?

### f. Allowable Costs

**Usually the allowable cost will include:**

- Indirect Cost/Non Recurring Budget: **Equipment and Accessories** (Upto 20% of proposed cost) list of equipment's, if required and justification in relevance to the project activities (Quotations supporting proposed equipment and accessories)
- Direct Costs/Recurring Budget (Realistic figures) : **Manpower** (Up to 50% of proposed cost), **Consumables** (Up to 20% of proposed cost), **Travel** (Inclusive of International travel, in case of International Collaborations) and **Outsourcing** (In case any activity to be outsourced)
- **Research Contingency and Overhead** of each Primary & Collaborating Partners (not exceeding 10% of the total Recurring Cost)
- **International collaborator(s) if any will be supported by BMGF directly, except travel expenses on actuals.**

***Note:** Justifications to be provided for roles of each aspect of manpower involved, consumables proposed, travel (Local and International in case if any), research contingency and trainings.

Budget heads without cap will be considered on case-to-case basis and based on call specifics by Technical Advisory Group (TAG).

### g. Warranty

The GCI Applicants shall warranty that the statements and particulars contained in the full proposal and supporting documents are correct. They have to further warrant that they are under no contractual restrictions or legal disqualifications or any other obligations which would prohibit them from undertaking the present Project, entering into any Agreement in this regard etc.

### h. Project Intellectual Property

The initiative is guided by the Memorandum of Understanding on the collaboration between the

Department of Biotechnology, Govt. of India and the Bill & Melinda Gates Foundation signed on July 18, 2012 and as such must consistent with the commitment that projects and investigators funded under initiatives make global access commitments to ensure the fruits of their research are available to those most in need. This will include, but not limited to, the ability to license any technology developed under this agreement to manufacturers in India subject to these global access commitments and to the relevant provisions of the Indian laws including specific requirements on licensing under the Patents Act 1970.

To this end, project IP means intellectual property generated during the conduct of the Project by the GCI applicants, but excluding the intellectual property generated before initiation of this Project and any IP generated outside the scope of this Project even during the term of this Project. The ownership and control of the intellectual property shall remain with the GCI grantee(s), or other collaborating organizations or institutions as agreed with the grantee, subject to any applicable local policies and the collaborative process described above, including arrangements between the grantee and other individuals or institutions.

GCI grantee(s) agree to conduct and manage the Project and the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, " Funded Developments") and any IP that arises in the manner that ensures " Global Access." Global Access requires that

1) The knowledge and information gained from the Project be promptly and broadly disseminated

2) The Funded Development is made available and accessible at an affordable price to people most in need within developing country.

Establishing suitable Global Access agreements among the GCI grantees will be a condition of receiving funding.

### i. Confidentiality

During the tenure of the Project, BIRAC will undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated from the Project for any purpose other than purposes in accordance this RFP. Please note that all proposals, documents, communications and associated materials submitted (collectively, "Submission Materials") will become the property of BIRAC and will be shared with other funding partners or potential funding partners.

Number of applications received and the countries from which they originated will be published. The proposals will be subject to confidential external review by independent subject matter experts and potential co-funders, in addition to in- house analysis.

## 4. Research Assurances

### a. Data access principles

BIRAC has the right to the technical data generated during the project for all the GCI funded projects.

The fund recipient shall permit BIRAC through its authorized representative access to the premises, during regular business hours, where the Project is being/shall be carried out and provide all information and produce or make available the concerned records for inspection and monitoring of the Project activity, required by BIRAC or the concerned committee under the RFP. BIRAC will as needed share this data with a Technical Advisory Group or with the funding partners.

### b. Indemnification

GCI applicants shall, at all times, indemnify and keep indemnified the Funding Agency/ BIRAC against any claims or suits in respect of any losses, damages or compensation payable in consequences of any accident, death or injury sustained by the employees of the Company or by any other third party resulting from or by any act, omission or operation conducted by or on its behalf. Further GCI applicants shall, at all times, indemnify and keep indemnified PMU or Funding Agency/ BIRAC against all claims/damages etc. by any infringement of any Intellectual Property Rights (IPR) while carrying out its responsibilities/work under the Project and this Agreement.

GCI applicants shall share the health information which develops through observational studies, surveys for the validation of the proposed solution into the programme setting and the like (the "Data") that would be beneficial to furthering the research goals with funders and global partners.

In the event of data sharing, there shall be a separate governing terms.

### c. Research Ethics and Regulatory Approvals

GCI Grantee(s) shall be responsible to obtain all the necessary requisite approvals, clearance certificates, permissions and licenses from the Government/local authorities for conducting its activities/ operations in connection with the Project.

**Contact us:**

Program Management Unit at BIRAC (PMU-BIRAC)

Biotechnology Industry Research Assistance Council

(A Government of India Enterprise)

First Floor, MTNL Building

9, CGO Complex, Lodhi Road,

New Delhi, 110003

Website: www.birac.nic.in

PMU-BIRAC website: www.birac.nic.in/grandchallengesindia

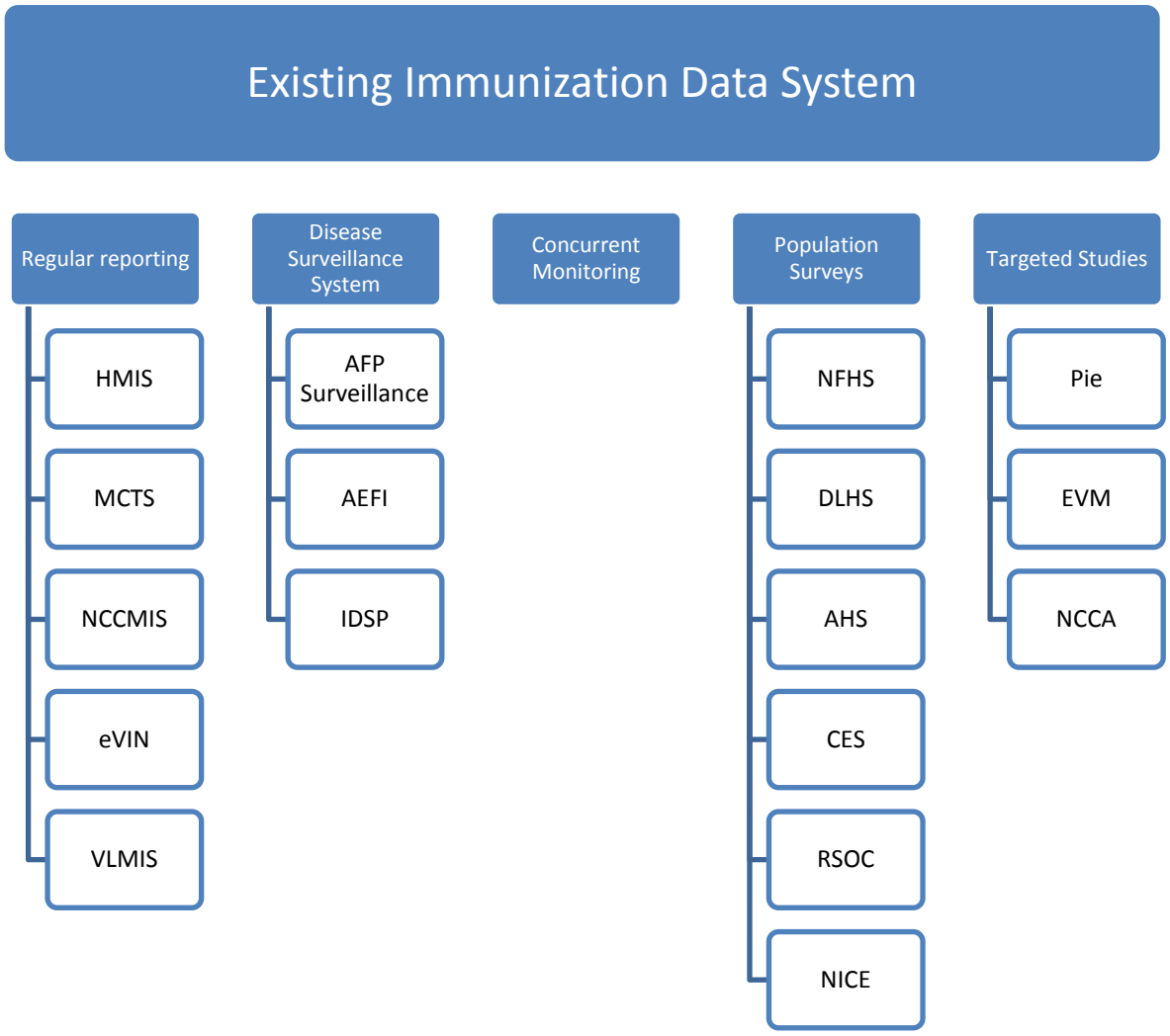
Telephone: +91-1124389600

For enquiries:

Please email: Mission Director, PMU- BIRAC at mdpmubmgf.birac@nic.in or call us at +91-1124389600 with the subject line: Grand Challenges India IDIA

## Annexure I

**Summary of existing immunization data system in India (adapted from National M&E Plan on Immunization, GoI)**




### *A. Regular reporting*

Health Management Information System (HMIS) and the Mother and Child Tracking System (MCTS) capture information on the overall health service delivery, which includes key UIP performance parameters. HMIS and MCTS are critical sources of information for the output and process level performance indicators for UIP. HMIS is a facility based monitoring system while MCTS is a beneficiary based monitoring system. HMIS reports data points on a monthly basis while MCTS monitors and reports on real time basis.

**Table 1: Regular reporting systems**

| M&E System Component | Methodology | Coverage |
|---|---|---|
| **Health Management Information System (HMIS)** | • All Districts report on Stock position (distributed/ received) on monthly basis<br>• All Districts report on Trainings/Program indicators on Quarterly basis<br>• All Districts report on Infrastructure/ Staff position/ Household survey done by ASHA every year on an Annual Basis<br>• All the Government facilities namely SC/ PHC/CHC/DH report on a monthly basis on the service delivery indicators<br>• All States report on trainings at state level on Quarterly basis, which includes ANM/Doctors given trainings.<br>• All States report Financial monitoring report (FMR) on quarterly basis<br>• All States report on Infrastructure/ Staffing on an Annual basis. | About 98 per cent of the districts have been reporting monthly data since 2009-10 |
| **Mother and Child Tracking System (MCTS)** | • For MCTS data is gathered at the Primary Health Centre and Block Level<br>• At Village Level: ASHA conducts a survey at the beginning of the Year to create a database of the beneficiaries (pregnant women and children) which also defines her scope of work for the year; Maintains and updates the information in a diary, and informs about the same to ANM<br>• At SC Level: ANM maintains and updates the Form no 6 in the Tally Register<br>• At Block Level and PHC Level: ANM/ Vaccine carrier collects service delivery data from ANM and submits it for data entry at the health facility to Data entry operator placed each at Block/PHC. The Data Entry Operator uploads the data on MCTS portal<br>• At State and District Level: State Data Officer and District Program Manager respectively ensure data quality at the given levels through verifications and audits | Over 99.5% Districts, 96% Health Blocks, 88% health facilities (Other than SHCs) and 94% SHC s report data in MCTS |
| **National Cold Chain Management Information System (NCCMIS)** | • NCCMIS Website www.nccvmtc.org has to be updated on every Saturday by the Refrigerator Mechanic of the District<br>• The website has to be reviewed by DMHO and DIO on a monthly basis<br>• Condemnation of Cold Chain Equipment has to be done on priority by circulating file to the District Collector | All states are required to upload the data. |
| **Electronic Vaccine Intelligence Network (eVIN)** | • Reporting of real time stock availability of vaccines and other logistics by the health workers/Cold chain handlers across all the levels of the Immunisation Supply Chain (ISC)<br>• Visibility of the vaccine stock levels and temperature status till the last cold chain mile.<br>• Uses mobile and web based technology platforms to do batch management based on EEFO and do batch tracking and tracing. | Currently, eVIN is getting rolled out across all 160 districts of three states UP, MP and Rajasthan. |

| M&E System Component | Methodology | Coverage |
|---|---|---|
| | • Make intelligent distribution decisions based on<br>– Consumption pattern for each commodities<br>– Availability of adequate stock levels recommended for each cold chain points<br>• Monitoring is carried out at all the levels from the National till the District level<br>• Monitoring the implementation of open vial policy is carried out.<br>• Monitoring of the temperature status for each cold chain equipment is carried out | Data on real time stock availability is getting reported from every rolled out district. |
| **Vaccine Logistics Management Information System (VLMIS)** | • State specific Vaccine logistics management information system<br>• Information on vaccine stock availability is collected at the district level and feed into web-based system at the end of every week.<br>• This information then gets visible at higher nodes.<br>• Based on the stock status, future projections and trend analysis is carried out. | Currently running in two states – Odisha and Bihar |

### *B. Disease Surveillance System*

Surveillance system for VPDs is crucial for (i) clinical management, (ii) epidemic/outbreak forecasting and (iii) impact assessment of the UIP. Currently, VPDs are covered as part of the HMIS reporting system. In addition, most VPDs are also notifiable diseases and need to be reported to local health authorities. Notification of VPDs is considered as a weak area and is in operation to varying degrees, especially in context of urban areas. In case of no cases being reported, in case of notifiable diseases, a NIL report has to be filed by each reporting unit. Public institutions and private practitioners/institutions are both liable to notify in case a VPD is reported. In addition, IDSP also investigates and reports incidences of VPDs, more specifically outbreaks but sporadic cases too.

**Table 2: Disease surveillance systems**

| M&E System Component | Methodology | Coverage |
|---|---|---|
| **AFP Surveillance** | • National Polio Surveillance Project (NPSP) was established to intensify surveillance for polio eradication through detection and investigation of childhood Acute Flaccid Paralysis (AFP).<br>• Methodology Followed:<br>- Collection, transport and reporting results of stool specimens<br>- Collection of specimens from contacts of afp cases<br>- India Polio virus laboratory network<br>- Sixty days follow-up examination<br>- AFP case classification and analysis | The surveillance system being currently practiced in India for detection of polio virus transmission is based on AFP case reporting, investigation, stool collection and laboratory investigation. Surveillance activities take place at the local level, District level, State level and the National Level. |

| M&E System Component | Methodology | Coverage |
|---|---|---|
| **AEFI surveillance** | • AEFI reactions can broadly be classified as 'serious AEFIs' (death, disability, cluster and hospitalization) which need to be reported immediately and investigated as per the laid down National AEFI guidelines.<br>• The other, i.e. 'minor AEFIs' are reported through monthly reporting systems in UIP in Government of India. These AEFI cases are reported in Form No. 6. Currently ASHA reports to ANM in case if a case emerges and ANM verifies the report and enters the data | State Surveillance Units (SSU) and District Surveillance Units (DSU) have that oversee Surveillance activities have been established in all states and UTs and districts (640) across India |
| **Integrated Disease Surveillance Project (IDSP)** | • Weekly disease surveillance data on epidemic-prone disease is collected from reporting units - SCs, PHCs, CHCs, hospitals (government and private) and medical colleges<br>• The data is collected in 'S' (syndromic), 'P'(probable) and 'L' (laboratory verified) formats using standard case definitions<br>• Weekly data is analysed by the SSUs/DSUs for disease trend<br>• Other VPD surveillance including (AFP, measles, JE, HIB, Rotavirus) | All states and districts are now required to constitute AEFI committees |

### *C. Concurrent Monitoring*

As part of the institutional arrangement, development partners have been playing a critical role in carrying out concurrent monitoring, which includes monitoring of routine immunisation at various levels like sessions, community level through visits to households, Block/PHC and district levels.

**Table 3: Concurrent monitoring**

| M&E System Component | Methodology | Coverage |
|---|---|---|
| Concurrent Monitoring | • Standard templates developed for monitoring the performance of a state. Support to State Immunisation divisions by obtaining the combined data and its analysis for Programme Management<br>• Monitoring is done at following levels:<br>– Session Monitoring<br>– House to House Monitoring (House in the vicinity of session sites are randomly checked to evaluate the outreach of Immunisation Sessions)<br>– Block/PHC level<br>– District level<br>– Cold chain points | All states covered |

Further a system of monitoring of training exists, where training data as captured in the HMIS is further analysed and developed as a training report by NIHFW/ National Cold Chain Vaccine Management Resource Centre (NCCVMRC) and National Cold Chain training Centre (NCCTC) for each state. This is collected by NIHFW for conducting field evaluations of trainings across states, and forms a basis for field evaluation of trainings outcomes.

### *D. Population based surveys*

The population based surveys, commissioned by the MoHFW along with development partners, play a critical role in UIP monitoring and evaluation by providing important programme estimates to assess the performance of the program over a period of time. The population based surveys are designed and commissioned primarily to provide information on overall health issues (including UIP). Apart from this, they also provide information on critical components such as knowledge and awareness levels of beneficiaries, ease of access to health services etc. Some of the key population based surveys that provide information on the Universal Immunization Programme include the National Family Health Survey (NFHS), District Level Health Survey (DLHS), Annual Health Survey (AHS) and Coverage Evaluation Survey (CES).

**Table 4: Population based surveys**

| M&E System Component | Methodology | Coverage |
|---|---|---|
| **National Family Health Survey (NFHS)** | NFHS is a periodic survey<br>• Uniform sampling design is adopted in each states<br>– Rural sample is selected in two stages: Selection of Primary Sampling Units (PSUs) with probability proportional to population size (PPS); Random selection of households within each PSU in the second stage.<br>– Urban sample, a three-stage procedure is followed: Selection of Wards through PPS sampling; One census enumeration block (CEB) is randomly selected from each sample ward; Households are randomly selected within each sample CEB<br>• Three types of questionnaires are filled:<br>– Household Questionnaire<br>– Woman's Questionnaire<br>– Village Questionnaire (Rural Areas)<br>– Biomarker | - 4th Round of NFHS will be conducted for all 29 States and the 6 Union Territories will be included for the first time<br>- NFHS-4 sample size is expected to cover 640 Districts as per Census 2011 (Approximately 568,200 households, up from about 109,000 households in NFHS-3)<br>- Yields a total sample of 625,014 women, 93,065 men and 265,653 children below age 5 will be eligible for the interview |
| **District Level Household Survey (DLHS)** | DLHS-4 sampling design is multi-stage stratified PPS sampling for each district<br>• Within each district, non-overlapping strata of urban and rural areas are formed (based on population/ HH size, percentage of SC/ ST population etc.)<br>• From each strata selection of representative Rural/ Urban primary sampling units(PSU) is done based on PPS<br>• This is followed by household listing and selection of | - DLHS 4 (Initiated in 2012-13) It covered - 20 states and 6 union territories. DLHS has now been discontinued. |

| M&E System Component | Methodology | Coverage |
|---|---|---|
| | households using systematic random sampling<br>• Household and Facility Survey coverage is conducted<br>• Two types of questionnaires are administered: 1. Household Questionnaire, 2. Woman's Questionnaire (Ever-married women (age 15-49) and never married women (age 15-24); Each facility has a separate questionnaire | |
| **Annual Health Survey (AHS)** | Baseline surveys are conducted in a sub-sample of Primary Sampling Units (PSUs) selected for the Annual Health Survey in each of the 284 districts across 9 AHS states during 2012-13. Three rounds conducted with last round in 2012-13. | - Study conducted only in districts of Empowered Action Group States (Bihar, Jharkhand, Madhya Pradesh, Chhattisgarh, Uttarakhand, Uttar Pradesh, Orissa and Rajasthan and Assam) |
| **Coverage Evaluation Survey (CES),** | Various methods of Sampling are used across states<br>• In each State rural- urban sample is taken in the ratio of 60:40<br>• Beneficiaries are covered under three broad heads:<br>– Pulse Polio Immunization: Under five Children<br>– Routine Immunization Coverage: 12 months to 23rd Months old children<br>– Maternal Coverage: Mothers who gave birth in last one year | - CES was conducted in 2009. It covered all States and Union Territories.<br>- Data was collected from 45,058 households, 22,604 mothers of children of age 12-23 months and 22,984 women who delivered during the last 12 months |
| **Rapid Survey of Children (RSOC)** | • RSOC was carried out to assess the situation of children and women in the country with special emphasis on access and utilization of services under the ICDS Scheme.<br>• Selection of Primary Sampling Units (PSU's) was similar to the National Family Health Survey 2005-06. | - RSOC was carried out across 29 states during November 2013<br>- Coverage was 105,483 households and 5630 Anganwadi centres (AWC). |
| **National Immunization Coverage Evaluation (NICE)** | • NICE was conducted to derive baseline and follow-up immunization coverage rates for Mission Indradhanush from nationally representative sample.<br>– NICE-I was conducted before Mission Indradhanush Round-1<br>– NICE-II was conducted before Mission Indradhanush Round-1<br>• The survey covered household to obtain data related to immunization coverage and its system determinants and health facilities to assess the availability, functioning and quality of immunization services | - NICE-I coverage was 12 States, 80 districts, 12,000 households and 800 health facilities<br>- NICE-II coverage was 12 States, 81 districts, 15,000 households and 1000 health facilities |

## *E. Targeted studies*

MoHFW along with other development partners also commissions targeted studies, which focus on addressing issues specific to vaccine management and delivery. They provide information on specialized aspects of service delivery such as the adequacy of the supply chain, cold storage, vaccine management and vaccine performance etc. The targeted studies identified and analysed in the context of UIP during this phase include the eVIN and PIE field assessment. PIE provides indicators on areas like vaccine coverage, vaccine management, waste management, impact assessment, AEFI whereas eVIN covers indicators in the areas like vaccine management, cold chain management and logistics.

**Table 5: Targeted studies**

| M&E System Component | Methodology | Coverage |
|---|---|---|
| **Post introduction evaluation (Pie)** | • PIE tool has been designed by the company to be self-administered by Health staff.<br>• Geographical selection possible selection criteria can be:<br>– A mix of regions/districts based on immunization programme performance (e.g. best, moderate, worst).<br>– Geographically diverse and representative regions /districts, and within those districts, health facilities selected on the basis of performance (e.g. best, moderate, worst)<br>– A variety of health facilities visited (i.e. including large and small health clinics, rural sites, urban sites, and outreach sites)<br>– A variety of sites that include those with high numbers of internally displaced persons, or ethnic minorities | PIE studies for Pentavalent vaccine have been conducted in eight states: Tamil Nadu, Kerala, Puducherry, Goa, Karnataka, Gujarat, Haryana and Jammu & Kashmir. It is normally conducted 6–12 months following introduction of the new vaccine |
| **Effective Vaccine Management Survey** | • Methodology is based on WHO principles of 'Learning by Doing'<br>• Participants (State Health Staff) are inducted in the use of EVM tool through training. The training consists of theoretical session, practical exercise of assessment in the nearby vaccine stores and training on supportive supervision.<br>• The process of selection of the sites to be assessed is done using the 'Site Selection Tool', provided in the Package | In 2012: Ten Indian states - Bihar, West Bengal, Arunachal Pradesh and Manipur, Himachal Pradesh, Andhra Pradesh, Karnataka and Tamil Nadu, Gujarat and Madhya Pradesh |
| **National Cold Chain Assessment** | • Methodology includes two major steps - Desk Review and Field Visits.<br>• The first step is reviewing the assessments of cold chain | Selection of states are done from EAG (Empowered Action Group), North Eastern and Better |

| M&E System Component | Methodology | Coverage |
|---|---|---|
| **(NCCA)** | logistics in the country through Desk Review of NCCMIS, CCO Review Meetings data and National EVM Data<br>• For Field Visit – 4 Core teams with each team having minimum of 2 members who conducts interviews of officials and technical staff members responsible for cold chain and vaccine management. On-site observations are also noted with regard to standards of site maintenance, vaccine management practices, cold chain equipment conditions and effective store management | performing states. In addition, GMSDs are also taken for assessment. |

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