



[Learning Beyond Boundaries:  
Linking Global Data to Life-Saving Action in an Era of Pandemics](#)

*A pandemic is not just a disease; it is a global health emergency that requires meaningful, responsible data sharing and multi-stakeholder cross-border collaboration. When pathogens cross boundaries, the information to manage the disease must see no boundaries.*

**Working Meeting – International Standard for Vaccine Administration Data  
18 February 2021, 10:30-12:00 EST/16:30-18:00 CET  
AGENDA**

(See the following pages for current list of participants; [international organizers are indicated in blue.](#))

- Introductions
- Urgency and Goals of the Proposed Project
- International Consensus Towards Harmonizing Vaccine Administration Data
  - Current Landscape and Scope of Project
  - CDISC INITIAL DRAFT of Core Data Elements for Vaccine Administration Record Information
- Questions
- Breakout Groups for Discussion of Core Data Elements
- Comments from Breakout Groups
- Actions and Next Steps

## PARTICIPANTS

**Ulrico Angeloni, MD** (ITALY) Ministry of Health, Directorate general for Prevention; member of the February 2020 rescue team in Wuhan, to re-inpatriate a group of Italian citizens suspected of having been affected by Covid-19; Focal point for Health Biosafety Training under the WHO International health regulations

**Brenda Baldwin, PhD** (USA) Microbiologist/Primary reviewer in the Office of Vaccines Research and Review (OVRR) since 2006. Leading expert in OVRR on the use of standardized data in studies. FDA representative for the development of a Vaccine Therapeutic Area User Guide (TAUG). Led and coordinated the development of a FDA technical specification guidance for vaccine specific data standardization, “Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review”

**Monica Bergagnoli, MD** (USA) Richard E. Wilson Professor of Surgery in the Field of Surgical Oncology at Harvard Medical School; member of the Gastrointestinal Cancer and Sarcoma Disease Centers at Dana-Farber/Brigham & Women’s Cancer Center; serves as the Group Chair of the Alliance for Clinical Trials in Oncology, a nation-wide NCI-funded clinical trials group; Chief Executive Officer of Alliance Foundation Trials, LLC, a not-for-profit corporation that conducts international cancer clinical trials; Past President and Chair of the Board of Directors of the American Society of Clinical Oncology (ASCO) and senior advisor to CancerLinQ

**Luigi Bertinato, MD, PhD** (ITALY) Head of the Office of the Scientific Secretariat to the President of the Italian National Institute of Health, Ministry of Health; Formerly WHO in Africa; DG Santè of the European Commission

**Jeffrey Brown, PhD** (USA), Associate Professor in the Department of Population Medicine (DPM) at Harvard Medical School and the Harvard Pilgrim Health Care Institute. His research focuses on new approaches to facilitate large-scale multi-institutional research through the use of distributed health data networks. This research formed the basis for several established research networks, including the FDA’s Sentinel System and PCORnet. Dr. Brown is the inventor of PopMedNet, an open-source software platform that facilitates creation and operation of distributed health data networks

**David A. Evans** (USA) President and CEO, Clinical Data Interchange Standards Consortium (CDISC); Former Chief Regulatory Compliance Officer, Accenture Life Sciences; Former CIO Octagon Research Solutions and Premier Research Worldwide; Founder, Research Data Corporation

**Hussein Ezzeldin, PhD** (USA) Senior Staff Fellow in the Office of Biostatistics and Epidemiology (OBE), Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA); currently, co-leads the Biologics Effectiveness and Safety Innovative Methods (BEST IM) initiative in OBE. BEST IM objective is developing a semi-automated adverse events (AEs) reporting infrastructure utilizing real-world data such as electronic health records. BEST IM comprises multiple workstreams, among them is advancing data standards needed to detect and report exposures and outcomes of interest to CBER

**Rhonda Facile** (USA) Vice President, Partnerships and Development, Clinical Data Interchange Standards Consortium (CDISC)

**Charles P. Friedman, PhD** (USA) Chair of the Department of Learning Health Sciences, Josiah Macy Jr. Professor of Medical Education at the University of Michigan Medical School; Professor of Information and Public Health; Founder, Learning Health Community; Former Deputy Director and Chief Scientific Officer, U.S. Office of the National Coordinator for Health IT

**Emanuela Maria Frisicale** (ITALY) Italian Ministry of Health, Directorate General of Prevention

**Francesco Gabrielli, MD** (ITALY) Head of the Italian Center for Telemedicine at the National Institute of Health

**Jose Galvez, MD** (USA), Deputy Director, Office of Strategic Programs, Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA); formerly Chief, Biomedical Translational Research Information System, NIH Clinical Center; prior Director of National Cancer Institute (NCI) Enterprise Informatics

**Esther Gil Zorzo** (SPAIN) President of Educatec Foundation; Diabetes Coordinator in HM Hospitals; Former President of the FEAD (National Federation for Diabetes Educators); Member of the Executive Committee of the FEND (Federation European Nurses Diabetes)

**Nick Halsey** (EU) Scientific Administrator, Healthcare Data, European Medicines Agency (EMA); EU topic lead for ICH M2 and E2B working groups; ISO TC215 WG6 member (NEN); Former HL7 patient safety working group co-chair; currently working on a data standardisation strategy and roadmap for the EU medicines regulatory network

**Luis Herrera Díaz-Aguado, JD** (SPAIN) Doctor in Law and civil servant of the Superior Body of Civil Administrators of the State; Advisor at the National Institute of Public Administration since 2011. He has managed in the State Administration and in the Autonomous Communities of Castilla-La Mancha and the Balearic Islands innovative programs and projects (quality management, citizen services, ICT or public employment).

**Georgina Humphreys, PhD** (UK) Clinical Data Sharing Manager, Open Research, Wellcome Trust; committed to maximising the benefits from research data; experience in clinical trials in UK academic institutions and in the field in East Africa; currently lead work on clinical trial transparency and data sharing; sit on ISRCTN Board, IDDO Ebola Data Sharing Steering Committee, and Covid-19 Therapeutics Accelerator Data Sharing Working Group; College Adviser at Green Templeton College, Oxford

**Virginia (Ginny) Hussong** (USA) Acting Chief, Data Standards Staff, CBER, FDA; Branch Chief for Data Standards, CBER since 2017, overseeing study data validation, tool support and training; previously managed the electronic submissions program and implementation of data standards within the Center, with a focus on eCTD and study data standards support and training

**Roberto Ieraci, MD, PhD** (ITALY) Medical doctor in infectious diseases and vaccines, City of Rome Health Care Unit n.1; member of the national training task force for the introduction of the new covid-19 vaccine in Italy

**Barbara Jauregui Wurst, MD MSc** (USA), Adjunct Professor, Global Vaccinology MPH course; Milken Institute School of Public Health, George Washington University; International Consultant; nineteen years of experience in public health program development and implementation, and clinical and operational research for governments and international organizations; PAHO/WHO Immunizations Unit, supporting Ministries of Health on informed decisions around vaccine-preventable diseases; Public Health and Academic Advisor, CDISC.

**Rebecca Kush, PhD** (USA) President, Catalysis; Chief Scientific Officer for Elligo Health Research; Founder and President Emeritus of the Clinical Data Interchange Standards Consortium (CDISC); Director on the Board, Learning Health Community; former HL7 Board Member and Member of U.S. Health IT Standards Committee

**Fco. Javier López Narbona** (SPAIN) Head of the Innovation Service in the Andalusia Region Ministry of Health, since 2004. From this position, he has coordinated and participated in Innovation projects, in collaboration with other regions, countries, the academic sector, other administrations and the private sector. He has held positions as Head of Quality at the Virgen del Rocío Hospital in Seville, various Management positions in Health Centers, Professor of Biostatistics, Health Education

**Julio Lorca, MD** (SPAIN) Medical Doctor and Civil servant; Director of Digital Health Development of DKV Health; catalyzation and development of the company's new lines in Health. Among others, those related to innovative trends in its field of action, enhancing the opportunities derived from e-Health, Telemedicine, AAL, Health Promotion 2.0, and others; member of the Board of several health associations and journals, national and international

**Claudia Marotta** (ITALY) Italian Ministry of Health, Directorate General of Prevention

**Brian Martin, MD** (USA) Principal Digital Health Analyst, The MITRE Corporation; formerly Founder and COB, Recentia Health; prior Director, Medical Informatics, GE Healthcare

**José Martínez Olmos** (SPAIN) Specialist in Preventive Medicine and Public Health; Professor at the Andalusian School of Public Health; Secretary General of Health in the Government of Spain from 2005 to 2011. In his government experience, he has promoted Laws such as the new General Public Health Law and the definitive universalization of public health. He has coordinated the work of all the Autonomous Communities in the response to the Flu pandemic

**Philip Payne, PhD, FACMI, FAMIA** (USA) Associate Dean for Health Information and Data Science and Chief Data Scientist at the Washington University School of Medicine; Janet and Bernard Becker Professor and founding Director of the School's Institute for Informatics (I2)

**Chris Price, MSc** (USA), Data Standards Technical Lead, Data Standards & Governance group, Roche; consults across the organization on topics relating to the governance, development and implementation of data standards throughout the organization; previously, Statistical Programming for multiple therapeutic areas; Working Groups Director at PHUSE responsible for the non-competitive, collaborative framework discussing topics and solutions relating to the advancement of computational science in medical research.

**Zeshan Rajput**, Principle in the Open Health Services division, The MITRE Corporation; Chief Clinical Lead of MITRE's oncology moonshot, supporting the ongoing development and deployment of mCODE, the minimal Common Oncology Data Elements, and CodeX, an HL7 FHIR Accelerator supporting mCODE; and, platform lead for CLIPPER, MITRE's Clinical Learning and Insights Platform for Pragmatic Evidence and Research, which aims to accelerate observational research by applying appropriate common data models, standardizing clinical and public health inquiries, and facilitating the use of advanced analytical techniques.

**Pablo Rivero** (SPAIN) Senior Health and Public Sector Advisor for Everis / NTT Data; Member of the Digital Health Roster of Experts, World Health Organization; Former Director General for the Agency for Quality and Innovation of the National Health System of Spain

**Carla Rodriguez-Watson, PhD, MPH** (USA), Director of Research, Reagan-Udall Foundation for the FDA; Infectious Disease Epidemiologist. The Foundation is an independent non-profit established by Congress to support FDA's mission to modernize product development, accelerate innovation, and enhance product safety. Research programs cultivate and leverage public-private partnership and network studies to accelerate and improve real world evidence generation for risk/benefit assessment of medical products.

**Francisco Ros, PhD** (SPAIN) President, First-Tech Engineering; Former Secretary of State for Telecommunications and the Information Society in the government of Spain; former Qualcomm Board Member

**Joshua Rubin, JD** (USA) Program Officer for Learning Health System Initiatives at the Department of Learning Health Sciences, University of Michigan Medical School; CEO of the Learning Health Community

**Borja Sanchez Garcia** (SPAIN) Minister of Science, Innovation and University of the Asturias Principality government in Spain; Senior Researcher at the Dairy Research Institute; Scientific Founder of Microviable Therapeutics SL

**Miguel Sebastián Gascón, PhD** (SPAIN) Bachelor's in Economics from the Universidad Complutense de Madrid and PhD in Economics from the University of Minnesota (USA); Consultant to IDB, World Bank, OECD, and IMF; appointed as Minister of Industry, Tourism and Trade of the Government of Spain from 2008 to 2011, with additional responsibilities on Telecoms and Energy; currently, Professor of Economic Analysis, Madrid's Universidad Complutense; very active in Spanish Media regarding Covid data and statistics

**Aziz Sheikh, OBE, FRSE, FMedSci**, (UK) Professor of Primary Care Research & Development and Director, Usher Institute, The University of Edinburgh; Director, Asthma UK Centre for Applied Research, HDR UK BREATHE Hub and NIHR Global Health Research Unit on Respiratory Health (RESPIRE), and Co-Director, NHS Digital Academy

**Paola Stefanelli** (ITALY) Director of the Laboratory of Vaccine preventable disease of the Infeccion Disease Department at the Italian National Institute of Health

**Paolo Stocco** (ITALY) Executive Board Member, EuroHealthNet, a not-for-profit partnership of organizations, agencies and statutory bodies working on public health, disease prevention, promoting health, and reducing inequalities

**Douglas Van Houweling, PhD** (USA) Professor Emeritus of Information, School of Information; Professor Emeritus in Service of Learning Health Sciences, University of Michigan Medical School