AI and Data Visitation

Addressing challenges in data transfers in clinical research within the framework of Open Science

Festival of Biologics: Clinical Trials

Basel, Switzerland, 3 November 2022

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The views presented here are those of the speaker's. They do not necessarily reflect those of any organisation. Francis gratefully acknowledges the work Ukraine Clinical Research Support Initiative (UCRSI), of the International Science Council's CODATA International Data Policy Committee (IDPC), and the EOSC-Future / RDA Artificial Intelligence & Data Visitation Working Group (AIDV-WG). Francis' EOSC Future / RDA Ambassador for Ethics & Law and the EOSC-Future projects are co-funded by the European Union's Horizon Programme call INFRAEOSC-03-2020 - Project ID 101017536. CODATA is funded by the International Science Council (ISC) and Horizon Europe as well as by other funding organisations. The Research Data Alliance (RDA) is funded by Horizon Europe as well as by other funding organisations (see here). Francis is grateful for the support provided by CODATA and the EOSC-Future and the RDA communities, structures, and secretariats.

The Vantage Point

- EU GCP Dir/Reg and Paediatric Regulation
- Chair WG, *Guidelines and Recommendations for European Ethics Committees* (Brussels 1995/7)
- Past member UNAIDS ERC
- Chair, WHO WGs on Guidelines for Ethics Committees & DSMBs
- Co-founder, FERCAP & SIDCER
- CIOMS Member
- Past Member, WHO GCP & ICTRP Committees
- Past Member, EORTC IRB; Chair, INCTR EC
- Member, EWG, European Academy of Paediatrics
- Co-founder, European Network for Research on Alternating Hemiplegia (ENRAH)
- EUROSOCAP, ENCCA, nEUroped, RESPECT, EBC

Current Activities

- Established in 2000 'PREP - Preparedness Planning for Clinical Research During Public Health Emergencies' in response to the SARS-CoV-2 pandemic
- Ambassador for Ethics and Law, European Open Science Cloud (EOSC) Future
- Chairman, EOSC Future / RDA Artificial Intelligence and Data Visitation Working Group (RDA AIDV-WG) & Member, COVID-19 Legal & Ethics Sub-Working Group
- Chairman, International Data Policy Committee (IDPC) & Member, Executive Committee, International Committee on Data (CODATA), International Science Council (ISC)
- Member, Regulatory and Ethics Work Stream (REWS), Global Alliance for Genomics and Health (GA4GH)
- Research Data Publishing Ethics Working Group, FORCE11 & The Committee on Publication Ethics (COPE)
- Co-founder, Ukraine Clinical Research Support Initiative (UCRSI)
- Member of the Data Stewardship Working Group, Virus Outbreak Data Network (VODAN) GO-FAIR

Data Science in Clinical Trials

'Data science is an interdisciplinary field that uses scientific methods, processes, algorithms and systems to extract or extrapolate knowledge and insights from noisy, structured and unstructured data, and apply knowledge from data across a broad range of application domains'

→Data is the currency of science & clinical trials (the most highly valued commodity in today's world)

→The value of data is determined through its utility

→ Data is science agnostic

Science & Data Governance in Clinical Trials

- How should we organize data within clinical research?
  - →to what purpose(s)
  - →within which framework(s)
  - →who is responsible? / who is governs the data?

Who Governs Science?
Who Determines Science Policy?

- Science and clinical trials governed from within

  → sponsors, clinics, universities, scientific organisations, individual scientists

- Science and clinical research governed from without

  → governments, inter-governmental organisations, funding organisations, communities, interest groups

→ What place should we provide to data within clinical trials?

UNESCO Recommendation on Open Science

Preamble

Recognizing the urgency of addressing complex and interconnected environmental, social and economic challenges for the people and the planet, including poverty, health issues, access to education, rising inequalities and disparities of opportunity, increasing science, technology and innovation gaps, natural resource depletion, loss of biodiversity, land degradation, climate change, natural and human-made disasters, spiralling conflicts and related humanitarian crises,

UNESCO Recommendation on Open Science

Preamble

Acknowledging the vital importance of science, technology and innovation (STI) to respond to these challenges by providing solutions to improve human well-being, advance environmental sustainability and respect for the planet's biological and cultural diversity, foster sustainable social and economic development and promote democracy and peace,

UNESCO Recommendation on Open Science

Preamble

Committed to leaving no one behind with regard to access to science and benefits from scientific progress by ensuring that the scientific knowledge, data, methods and processes needed to respond to present and future global health and other crises are openly available for all countries, in accordance with the rights and obligations, including the exceptions and flexibilities, under applicable international agreements,

UNESCO Recommendation on Open Science

4. As per the 2017 UNESCO Recommendation on Science and Scientific Researchers, the term 'science' signifies the enterprise whereby humankind, acting individually or in small or large groups, makes an organized attempt, in cooperation and in competition, by means of the objective study of observed phenomena and its validation through sharing of findings and data and through peer review, to discover and master the chain of causalities, relations or interactions; brings together in a coordinated form subsystems of knowledge by means of systematic reflection and conceptualization; and thereby furnishes itself with the opportunity of using, to its own advantage, understanding of the processes and phenomena occurring in nature and society.

UNESCO Recommendation on Open Science

6. For the purpose of this Recommendation, **open science** is defined as an inclusive construct that combines various movements and practices aiming to make multilingual scientific knowledge openly available, accessible and reusable for everyone, to increase scientific collaborations and sharing of information for the benefits of science and society, and to open the processes of scientific knowledge creation, evaluation and communication to societal actors beyond the traditional scientific community. It comprises all scientific disciplines and aspects of scholarly practices, including basic and applied sciences, natural and social sciences and the humanities, and it builds on the following key pillars: open scientific knowledge, open science infrastructures, science communication, open engagement of societal actors and open dialogue with other knowledge systems.

The Challenges to Clinical Trials in Disruptive/Disaster Situations

Two recent events: COVID-19 & Ukraine

- The vulnerability of persons affected by the disruption
- The lack of structure
- The lack of predictability
- The difficulty to organise
- Ongoing threats
- Angst

The Challenge of Clinical Research in Disruptive Situations

- A tendency to respond with actions based on what we already know
- A view that clinical research (science) is a luxury
- A view that science (e.g., human experimentation) is unacceptable in disruptive situations
  e.g., Nuremberg Code, Geneva Convention

Understanding Clinical Research in Disruptive Situations

- We must learn (including *in* situ) from disruptive situations to prepare for, and respond to, future disruptive situations that are similar
- We must learn (including *in situ*) from disruptive situations to respond to the situations themselves in real time

→ Requires data generation and data processing

→ Requires data policy

What is the medical research enterprise

- An essential structure within a society for responding to the realities and/or threats of disease, suffering, and the healthcare needs of individuals and populations
- An essential element in society for the following:
  - Medicine, including the creation of medical knowledge as well as responding to individual and population health needs
  - Science, contributing to specific knowledge on human biology and health as well as to general knowledge about ourselves and the world
  - Education, as a foundation for medical education while also contributing to many other related and ancillary sciences
  - Profession, as a framework for essential professions in society
  - Public health, as a sine qua non for public health systems to ensure that the diseases and health of populations are addressed in the specificity and generality
  - Industry, it contribute to an important socio-economic force in society, developing wealth through its generation of knowledge, products, and a healthy workforce

→It is impossible to imagine a healthy society without a healthy medical research enterprise

We need to reconsider the role of data in clinical trials within a framework of Open Science if we are to make clinical research more relevant and applicable.