Data sharing and the responsible conduct of research

Sharing industry experiences as part of the research transparency environment

A WCRI Symposium

co-convened by

Tatjana Poplazarova
Vice President, Head of Medical Governance and Bioethics, GSK Vaccines
Wavre, Belgium

and

Francis P. Crawley
Executive Director, Good Clinical Practice Alliance - Europe (GCPA)
Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
Leuven/Brussels, Belgium

6th World Congress of Research Integrity
Hong Kong, China; 2-5 June 2019

SYMPOSIUM OBJECTIVES

- Share experiences on data sharing and research integrity from industry and academic researchers, an independent data custodian, a public funder, a journal editor, and a publisher, as well as a representative from patient initiatives

- Discuss insights into developing pathways to responsible data disclosure

- Attempt to answer the questions:

  ➤ What are the challenges and pathways to the disclosure of scientific data?

  ➤ What are the ethical requirements and the scientific utility of sharing research data?

  ➤ Who is served by sharing research data?

  ➤ What are the responsibilities of researchers and their institutions when disclosing and sharing research data?

  ➤ In what ways does sharing research data promote research integrity?

AGENDA & CONTRIBUTORS

Introductory comments	10'	**Tatjana Poplazarova** Vice President, Head of Medical Governance and Bioethics, GSK Vaccines; Wavre, Belgium
		Francis P. Crawley Executive Director, Good Clinical Practice Alliance - Europe (GCPA) Strategic Initiative for Developing Capacity in Ethical Review (SIDCER); Brussels, Belgium
Panel 1 - Responsible data custodian ship, data protection & management, data sharing *(chaired by Tatjana)*	20'	**Rebecca Li** Executive Director, Vivli; Cambridge, Massachusetts, USA
		Priya Pavithran Director, Publications & Public Disclosure, GSK Vaccines; Wavre, Belgium
		Slávka Baróniková Collaborative Research Lead, Global Medical Affairs, Takeda; Brussels, Belgium
		Karen Woolley Global Lead, Patient Partnerships, Envision Pharma Group Editorial Board, Research Integrity and Peer Review Adjunct Professor, University of Queensland Adjunct Professor, University of the Sunshine Coast; Australia
Audience input	10'	
Panel 2 – The way forward: Ensuring the integrity of health-research data for patients, the public, and a sustainable & innovative scientific future *(chaired by Francis)*	15'	**Suzanne Farley** Head of Research Integrity at Springer Nature Publishing; London, England
		Haihong Zhang Office Director of Peking University Human Research Protection Program Peking University; Beijing City, China
		Dorota Goble UK National Institute of Health Research (NIHR) EViR (Ensuring Value in Research); Southampton, England
Audience input	10'	
Live panel & audience discussion	20'	
Concluding comments	5'	**Tatjana Poplazarova**

DISCLOSURES

The views and opinions expressed in the following slides are those of the individual presenters and should not necessarily be attributed to any organization with which the presenters are employed or affiliated, unless expressly stated.

- Tatjana Poplazarova is an employee of the GSK Group of Companies
- Francis P. Crawley has advised public and patient organisations on research integrity and received European public funding in his roles as an Ethics Advisor and Data Protection Officer
- Rebecca Li is an employee of Vivli and on Faculty at the Harvard Medical School
- Slávka Baróniková is a consultant to Shire (now part of Takeda)
- Priya Pavithran is an employee of the GSK Group of Companies
- Karen Woolley: financial – employee Envision Pharma Group; non-financial – advocate for ethical publication practices and patient involvement in medicines development
- Suzanne Farley is an employee of Springer Nature
- Haihong Zhang is a faculty member/employee at Peking University, no relationship with any industries
- Dorota Goble is an employee of the National Institute for Health Research (NIHR) UK
- Editorial support for presentations was provided by Veronique Delpire and Mandy Payne of Words & Science, Brussels, Belgium

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INTRODUCTION
Data sharing today

TATJANA POPLAZAROVA

Vice President, Medical Governance and Bioethics, GSK Vaccines

- **How much data?** CSDR (est. 2014) hosts data from 3722 clinical trials =>42 publications; Vivli (est. 2018) hosts 3900+ clinical trials = 1.9m participants, no publications yet. Other platforms e.g. YODA, IDDO

- **Who is sharing data?** CSDR and Vivli each host data from 19 industry and non-profit orgs; Vivli also hosts academic research

- **How does it work?** Researchers send research proposal to the portal for review. If approved, access given via secure portal. *Issue: balance between data protection and usability*

- **Who pays?** Sponsors/funders of the original research pay the platform to share their data. No cost to researchers for using shared data

- **How is shared data being used?** Mostly novel research, few requests for reproducibility research

FRANCIS P CRAWLEY
Good Clinical Practice Alliance – Europe (GCPA)
Strategic Initiative for developing capacity in ethical review (SIDCER)
Perspective from: Ethicists, Ethics Committees, and NGOs/IGOs

Key points

▶ Ensure the integrity of the data

▶ Ensure the integrity of the presentation of the data

▶ Ensure the confidentiality and utility of the data

Challenges

▶ Implementing ALCOA+ and FAIR in data management systems

▶ Data for science, data for prescribers, data for patients, data for marketing, data for public health

▶ Data protection and data sharing in a wide variety of settings

The Way Forward

▶ Building communities and systems of trust for data in health-related research The SIDCER Experience in FERCAP, FECCIS, PABIN, and FLACEIS

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PANEL 1
Responsible data custodianship, Data protection and management, Data sharing

Rebecca Li, Executive Director, Vivli

Priya Pavithran, Director, Publications & Public Disclosure, GSK Vaccines

Slávka Baróniková, Collaborative Research Lead, Global Medical Affairs, Takeda

Karen Woolley, Global Lead, Patient Partnerships, Envision Pharma Group

REBECCA LI
Vivli
Perspective from: Global Data Sharing Platform

Key points

▶ Global registries and data sharing policies are moving the culture towards greater sharing of Individual Participant level data (IPD)

▶ Various Platforms (such as Vivli, CSDR, YODA, IDDO and others) offer a mechanism for researchers to share data

▶ To move beyond

The way forward

▶ For data sharing to be embraced, there must be **concrete benefits** for those that share and the access process user-friendly

Challenges

▶ Greater awareness of the data sharing platform resource offerings among qualified researchers

▶ Integration of datasets across various sources remains a barrier

▶ Data standards implementation

PRIYA PAVITHRAN
GSK Vaccines
Perspective from: Data Providers (Industry)

Key points

▶ Enabling data access for maximum benefits

▶ Patient privacy and progression of research

▶ Measuring the impact of data sharing initiatives

Challenges

▶ Data: what, when and how?

▶ Different regulations, standards to apply

▶ Quantifying the benefits, costs, time

The Way Forward

▶ Harmonize data sharing standards to improve utility, anonymization

▶ Awareness among stakeholders of their role in responsible data sharing

▶ Communicate how data sharing benefits scientific research

SLÁVKA BARÓNIKOVÁ

Takeda

Perspective from: Data Providers (Industry)

Key points

▶ CT protocol,results/CSRs posting on Public Registries

▶ Responsible patient level data sharing

▶ Patient level data sharing vs CT participant privacy

The Way Forward

▶ Harmonization of CT disclosure requirements

▶ Collaborative effort of CT sponsors & funders

  ▶ sharing acquired knowledge

  ▶ developing data sharing guidance

Challenges

▶ Public registries: inconsistencies between multiple/simultaneous postings of the same CT -> different data disclosure requirements

▶ Disclosure of interventional vs non-interventional/ observational studies (incl. drug/disease registries)

▶ Informed Consent - data sharing language

▶ Data request & sharing processes (data anonymization& sharing format)

▶ De-identification of CT participants (e.g. rare disease setting) vs. need to retain data utility

KAREN WOOLLEY
Envision Pharma Group
Perspective from: Data Providers & Beneficiaries (Public Institutions & Patients)

Key points

▶ Put the PUBLIC in PUBLIC-ations

▶ Dr Google is winning
(and patient safety is not)

▶ Burden or benefit?

Challenges

▶ Access & understand publications

▶ Trust and transparency

▶ Adopt & reward innovation

The way forward

▶ Everyone wins: Industry standard and toolkit for plain language summaries of publications, co-created with and for patients, available at www.envisionthepatient.com/plstoolkit

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PANEL 2

The way forward
Ensuring the integrity of health-research data for patients, the public, and a sustainable & innovative scientific future

Suzanne Farley, Head of Research Integrity at Springer Nature Publishing

Haihong Zhang, Office Director of Peking University Human Research Protection Program, Peking University

Dorota Goble, UK National Institute of Health Research (NIHR), EViR (Ensuring Value in Research)

SUZANNE FARLEY
Springer Nature
Perspective from: Those Setting the Ethics Standards

Key points

- Many researchers willing to share data but lack time & expertise to organise it in a reusable way

- Articles with underlying data available cited more

- Data sharing facilitates prevention, detection and resolution of research integrity problems

Challenges

- Standardising and enforcing data-sharing policies

- Peer-review of data

- Integrating publisher platforms with data repositories

The Way Forward

- Collaboration between funders, institutions, publishers, infrastructure providers and research communities

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HAIHONG ZHANG
Peking University Health Science Center
Perspective from: Those Setting the Ethics Standards

Key points

▶ Data regarded as treasure having great value for future research & other activities

▶ Guarantee more responsible data sharing: rights and responsibilities of stakeholders

▶ Data sharing: from ethics norms to practice

The Way Forward?

▶ Quality control and administrative mechanisms: high quality, sharable data

▶ Streamline data sharing: appropriate incentives, practical guidelines, supportive infrastructures

Challenges

▶ Culture perspective: privacy, data utility

▶ Absent of data protection regulation and guidelines in China

▶ Infrastructure obstacles

▶ Possible concerns: reputation

DOROTA GOBLE
National Institute for Health Research UK
Perspective from: Those Setting the Ethics Standards

Key points

▶ Reuse of data increases transparency, quality, and efficiency…

▶ Publicly funded research data does not (morally) just belong to researchers

▶ We have to think carefully about how and when we share

Challenges

▶ …but we don't know if there is a demand for it

▶ …but researchers are key value creators, and rely on reward and recognition

▶ …but we don't know how. We need new ethical codes

The way forward

▶ A new social understanding between researchers, patients/public, and taxpayers

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Live panel & audience discussion

CONCLUDING COMMENTS: how were the symposium objectives achieved & the way forward

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