Clinical Trial Data, Information, and Results

Overview of the Current Landscape

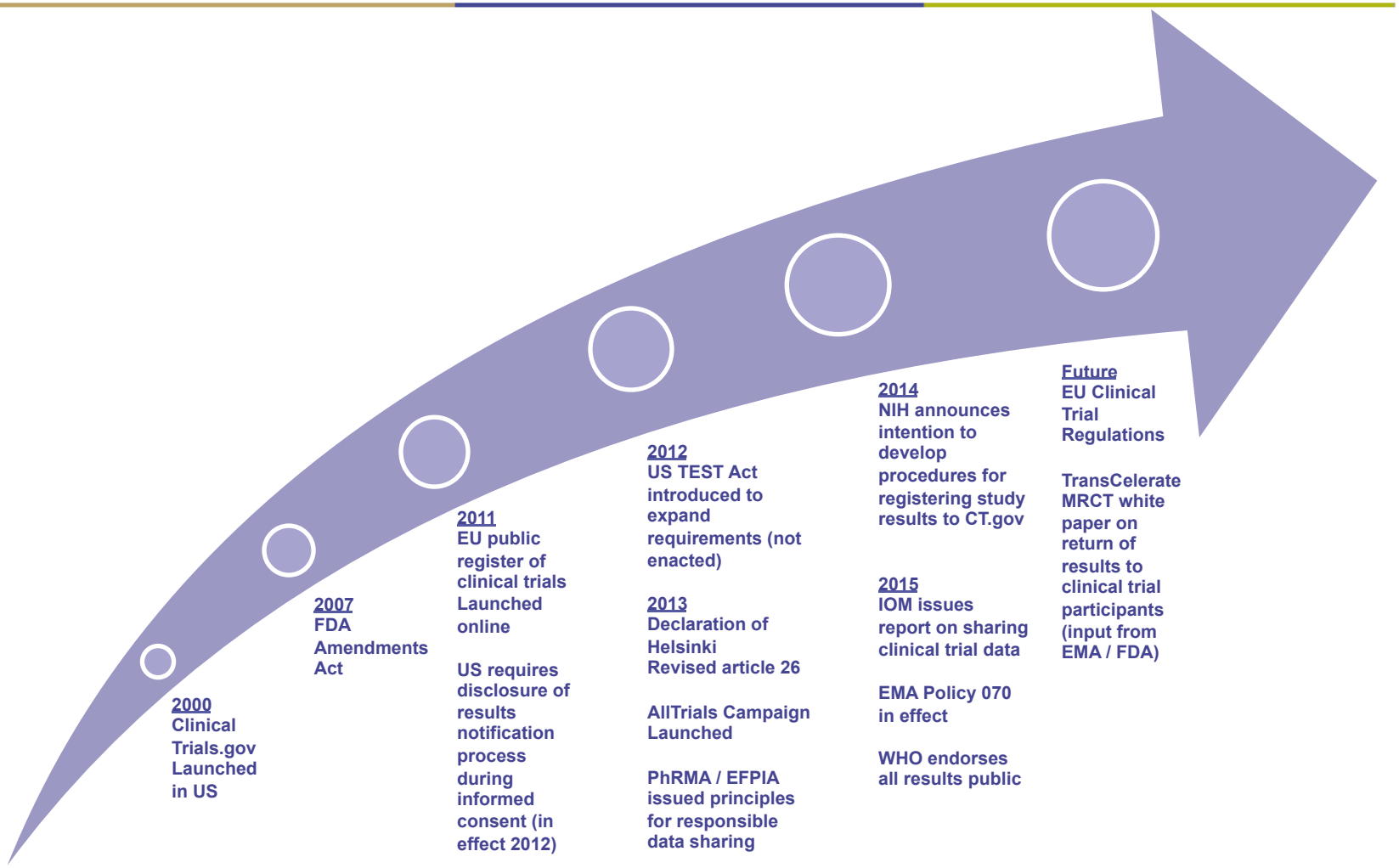
Dr. Paul Chew
Senior Vice President , Group Chief Medical Officer
May 2015

SANOFI

Agenda

- Data sharing landscape
- Our commitment to share

Escalating Demands for Clinical Trial Transparency



Courtesy of TransCelerate BIOPHARMA INC

SANOFI

The Data Sharing Landscape

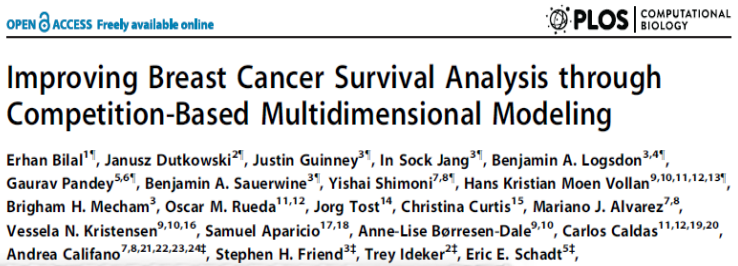
VOLUME 29 · NUMBER 9 · MARCH 20 2011

JOURNAL OF CLINICAL ONCOLOGY | E D I T O R I A L S

Clinical Research: Show Us the Data

Alberto Ocana, *Princess Margaret Hospital, Toronto, Canada; Albacete University Hospital and Asociacion Española Contra El Cancer Unit, Albacete, Spain*
Eitan Amir, *Princess Margaret Hospital, Toronto, Canada*
Bostjan Seruga, *Institute of Oncology Ljubljana, Ljubljana, Slovenia*

See accompanying editorial on pages 1091 and article on page 1204



OPEN ACCESS Freely available online | PLOS COMPUTATIONAL BIOLOGY

Improving Breast Cancer Survival Analysis through Competition-Based Multidimensional Modeling

Erhan Bilal[1¶], Janusz Dutkowski[2¶], Justin Guinney[3¶], In Sock Jang[3¶], Benjamin A. Logsdon[3,4¶], Gaurav Pandey[5,6¶], Benjamin A. Sauerwine[3¶], Yishai Shimoni[7,8¶], Hans Kristian Moen Vollan[9,10,11,12,13¶], Brigham H. Mecham[3], Oscar M. Rueda[11,12], Jorg Tost[14], Christina Curtis[15], Mariano J. Alvarez[7,8], Vessela N. Kristensen[9,10,16], Samuel Aparicio[17,18], Anne-Lise Børresen-Dale[9,10], Carlos Caldas[11,12,19,20], Andrea Califano[7,8,21,22,23,24‡], Stephen H. Friend[3‡], Trey Ideker[2‡], Eric E. Schadt[5‡],

…engineering, University of California San Diego, La … of Public Health Sciences, Fred Hutchinson Cancer … ahn School of Medicine at Mount Sinai, New York, … Mount Sinai, New York, New York, United States of … America, **8** Center for Computational Biology and … for Cancer Research, Oslo University Hospital, Oslo, …, University of Oslo, Oslo, Norway, **11** Cambridge … ridge, Cambridge, United Kingdom, **13** Department … laboratory for Epigenetics and Environment, Centre

CNBC.com

FDA sees huge opportunities in opening up drug data

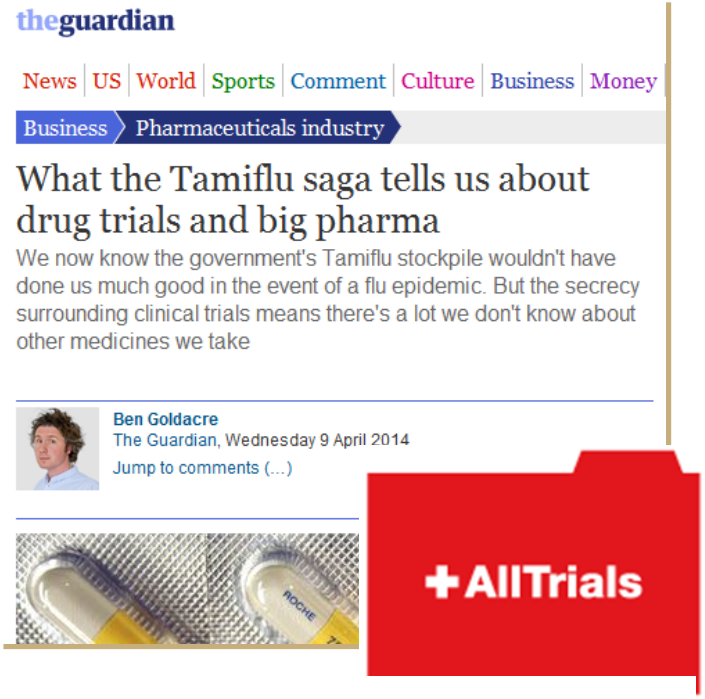
LONDON | Mon Dec 5, 2011 9:23pm IST

(Reuters) - Regulators and drugmakers need to find ways to make more clinical data openly available, since vital knowledge about fighting disease is often locked away in confidential databases, the head of the U.S. drugs watchdog said on Monday. Food and Drug Administration (FDA) Commissioner Margaret Hamburg said opening up data to public scrutiny needed to be done selectively, given legitimate concerns among companies over commercial confidentiality, but more could still be done.

T. Savage & Vickers, 2009. PLoS One

The Data Sharing Landscape

- Mounting public pressure for clinical trial transparency
  - "Transparency Campaigners"
- 2013 - EMA proposal to release all data they hold once a drug has been approved
- Industry responds - concerns competitiveness, IP, data protection



Scrip Regulatory Affairs

WHO endorses 12-month timeline for reporting clinical trial results, wants all results to be public

Today

Vibha Sharma

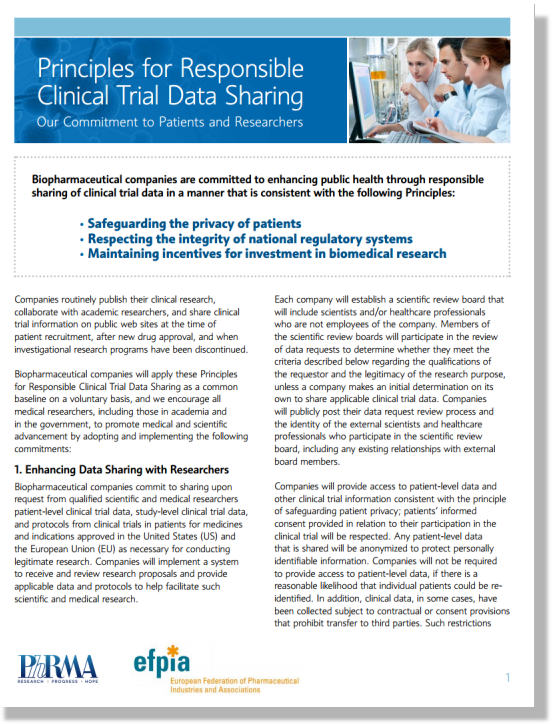
The Data Sharing Landscape

- PhRMA working group drafted set of voluntary guiding principles for the Responsible Sharing of Clinical Trial Data.

- Adopted by PhRMA and EFPIA in July 2013.
- Came into effect Jan 1, 2014
- Five 'commitments'

  1. Enhancing Data Sharing with Researchers
  2. Enhancing Public Access to Clinical Study Information
  3. Sharing Results with Patients who Participate in Clinical Trials
  4. Certifying Procedures for Sharing Clinical Trial Information
  5. Reaffirming Commitments to Publish Clinical Trial Results

- Academic and Quasi-government Organizations have proposed recommendations



Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

Companies routinely publish their clinical research, collaborate with academic researchers, and share clinical trial information on public web sites at the time of patient recruitment, after new drug approval, and when investigational research programs have been discontinued.

Biopharmaceutical companies will apply these Principles for Responsible Clinical Trial Data Sharing as a common baseline on a voluntary basis, and we encourage all medical researchers, including those in academia and in the government, to promote medical and scientific advancement by adopting and implementing the following commitments:

1. Enhancing Data Sharing with Researchers

Biopharmaceutical companies commit to sharing upon request from qualified scientific and medical researchers patient-level clinical trial data, study-level clinical trial data, and protocols from clinical trials in patients for medicines and indications approved in the United States (US) and the European Union (EU) as necessary for conducting legitimate research. Companies will implement a system to receive and review research proposals and provide applicable data and protocols to help facilitate such scientific and medical research.

Each company will establish a scientific review board that will include scientists and/or healthcare professionals who are not employees of the company. Members of the scientific review boards will participate in the review of data requests to determine whether they meet the criteria described below regarding the qualifications of the requestor and the legitimacy of the research purpose, unless a company makes an initial determination on its own to share applicable clinical trial data. Companies will publicly post their data request review process and the identity of the external scientists and healthcare professionals who participate in the scientific review board, including any existing relationships with external board members.

Companies will provide access to patient-level data and other clinical trial information consistent with the principle of safeguarding patient privacy; patients' informed consent provided in relation to their participation in the clinical trial will be respected. Any patient-level data that is shared will be anonymized to protect personally identifiable information. Companies will not be required to provide access to patient-level data, if there is a reasonable likelihood that individual patients could be re-identified. In addition, clinical data, in some cases, have been collected subject to contractual or consent provisions that prohibit transfer to third parties. Such restrictions

PhRMA RESEARCH · PROGRESS · HOPE

efpia European Federation of Pharmaceutical Industries and Associations

1

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

MRCT Multi-Regional Clinical Trials
The MRCT Center at Harvard

SANOFI

The Data Sharing Landscape

- EMA, after stakeholder feedback from the industry, has re-thought it's data sharing proposals
- Policy 070 final Oct 2014 and came into effect Jan 1 2015
- Clinical Study Reports will become publically available upon decision of the application

SANOFI

Sanofi is Committed to Sharing Clinical Trial Data, Information, and Results

- **Making clinical trial data, information and results available to researchers, promises to advance science and medicine, contribute to improvements in public health and improve knowledge about, and trust in, pharmaceutical product development**

- **It is equally important to protect the privacy of the participants in our clinical trials as well as to maintain incentives for investment in biomedical research**