



Available online at  
**ScienceDirect**  
www.sciencedirect.com

Elsevier Masson France  
**EM|consulte**  
www.em-consulte.com



GIENS WORKSHOPS 2015 / *Clinical Pharmacology*

## “Big data” and “open data”: What kind of access should researchers enjoy?☆



Gilles Chatellier<sup>a,\*</sup>, Vincent Varlet<sup>b</sup>,  
Corinne Blachier-Poisson<sup>c</sup>, the participants of Giens  
XXXI, Round Table No. 6, Nathalie Beslay<sup>d</sup>,  
Jehan-Michel Behier<sup>e</sup>, David Braunstein<sup>f</sup>,  
Mireille Caralp<sup>g</sup>, Brigitte Congard-Chassol<sup>h</sup>,  
Isabelle Diaz<sup>i</sup>, Laure Fournier<sup>a</sup>, Anne Josseran<sup>h</sup>,  
Philippe Lechat<sup>j</sup>, Cinira Lefevre<sup>k</sup>,  
Franck von Lennep<sup>l</sup>, Karine Levesque<sup>m</sup>,  
Philippe Maugendre<sup>n</sup>, Guillaume Marchand<sup>o</sup>,  
Didier Menecier<sup>p</sup>, Nicholas Moore<sup>q</sup>,  
Sophie Ravoire<sup>r</sup>, Christine Riou<sup>s</sup>

<sup>a</sup> Hôpital européen Georges-Pompidou, AP–HP, 20, rue Leblanc, 75908 Paris cedex 15, France

<sup>b</sup> LeLabEsanté, 75000 Paris, France

<sup>c</sup> AMGEN, 92650 Boulogne-Billancourt, France

<sup>d</sup> Beslay + Avocats, 75008 Paris, France

<sup>e</sup> Takeda France, 92977 Paris-La-Défense, France

<sup>f</sup> Hôpital La Timone, AP–HM, 13385 Marseille, France

<sup>g</sup> Inserm Transfert, 75013 Paris, France

<sup>h</sup> SNITEM, 92400 Courbevoie, France

<sup>i</sup> LEEM/ARIIS, 75858 Paris, France

<sup>j</sup> DRCD, hôpital Saint-Louis, AP–HP, 75475 Paris, France

<sup>k</sup> Bristol-Myers-Squibb, 92500 Rueil-Malmaison, France

<sup>l</sup> DREES, 75350 Paris, France

<sup>m</sup> Abbott Vascular, 94518 Rungis, France

<sup>n</sup> Sanofi France, 94255 Gentilly, France

<sup>o</sup> DMD Santé, 51100 Reims, France

<sup>p</sup> Direction centrale du service de santé des armées, 94160 Saint-Mandé, France

DOI of original article: <http://dx.doi.org/10.1016/j.therap.2016.01.004>.

☆ Articles, analyses and proposals from the Giens workshops are those of the authors and do not prejudice the proposition of their parent organization.

\* Corresponding author.

E-mail address: [gilles.chatellier@aphp.fr](mailto:gilles.chatellier@aphp.fr) (G. Chatellier).

<http://dx.doi.org/10.1016/j.therap.2016.01.005>

0040-5957/© 2016 Société française de pharmacologie et de thérapeutique. Published by Elsevier Masson SAS. All rights reserved.

<sup>q</sup> Université de Bordeaux, 33076 Bordeaux, France

<sup>r</sup> SR Consulting, 75015 Paris, France

<sup>s</sup> CHU de Rennes, 35033 Rennes, France

Received 17 December 2015; accepted 21 December 2015

Available online 3 February 2016

## KEYWORDS

“Big data”;  
“Open data”;  
Anonymization;  
Connected objects;  
Data storage

**Summary** The healthcare sector is currently facing a new paradigm, the explosion of “big data”. Coupled with advances in computer technology, the field of “big data” appears promising, allowing us to better understand the natural history of diseases, to follow-up new technologies (devices, drugs) implementation and to participate in precision medicine, etc. Data sources are multiple (medical and administrative data, electronic medical records, data from rapidly developing technologies such as DNA sequencing, connected devices, etc.) and heterogeneous while their use requires complex methods for accurate analysis. Moreover, faced with this new paradigm, we must determine who could (or should) have access to which data, how to combine collective interest and protection of personal data and how to finance in the long-term both operating costs and databases interrogation. This article analyses the opportunities and challenges related to the use of open and/or “big data”, from the viewpoint of pharmacologists and representatives of the pharmaceutical and medical device industry.

© 2016 Société française de pharmacologie et de thérapeutique. Published by Elsevier Masson SAS. All rights reserved.

## Abbreviations

ADNI	Alzheimer’s disease neuroimaging program
BDW	biomedical data warehouses
CCAM	medical classification for clinical procedures ( <i>classification commune des actes médicaux</i> )
CDW	clinical data warehouses
CépiDC	Epidemiology Centre on the Medical Causes of Death ( <i>Centre d’épidémiologie sur les causes médicales de décès</i> )
CNAMTS	<i>Caisse nationale d’assurance maladie des travailleurs salariés</i>
CNIL	data protection watchdog ( <i>Commission nationale informatique et libertés</i> )
CNSA	National Solidarity Fund for Autonomy ( <i>Caisse nationale de solidarité pour l’autonomie</i> )
CPRD	clinical practice research datalink
DNA	deoxyribonucleic acid
eCTD	electronic common technical document
EGB	general samples of beneficiaries
EHR4CR	Electronic Health Records for Clinical Research
EMA	European Medicines Agency
GAFAMS	Google, Apple, Facebook, Amazon, Microsoft and Samsung
HEGP	Georges-Pompidou European Hospital ( <i>Hôpital européen Georges-Pompidou</i> )
IMI	innovative medicines initiative
INDS	National Institute of Health Data ( <i>Institut national des données de santé</i> )
INSERM	<i>Institut national de la santé et de la recherche médicale</i>
PMSI	medicalization of information systems programme ( <i>programme de médicalisation des systèmes d’information</i> )

SHRINE	Shared Health Research Information Network
SNDS	national system of health data
SNIRAM	French national health insurance information systems ( <i>Système national d’information inter-régimes de l’assurance maladie</i> )

## Introduction

It is now possible to analyse several petabytes of data on condition of having access to powerful computers and appropriate algorithms. The real difficulty lies elsewhere. In all areas of activity, the citizens of the world do not fully control nor understand what is being collected, analysed and used, sometimes without their knowledge. Moreover, the global availability and dissemination of such data raise legal issues, with legislation differing from one country to another. Finally, some countries fund the development and operation of large databases, possibly with the support of private contributions, while others do not view such investments as a priority.

The healthcare field has also witnessed the explosion of massive data whose computer processing aims to provide new information, which is useful to society and the sick, while guaranteeing citizens – whether current or future patients – and researchers greater confidentiality and improved access to data... two contradictory objectives! The aim of this Round Table was to shed light on concepts hidden behind the terms “big data” and “open data” and to underscore certain difficulties or delays affecting our country in this area, against a backdrop of fierce international competition, while also drawing attention to the methodological difficulties to be factored in so as to avoid reaching the kind of inappropriate conclusions

Download English Version:

<https://daneshyari.com/en/article/2578584>

Download Persian Version:

<https://daneshyari.com/article/2578584>

[Daneshyari.com](https://daneshyari.com)