Munich Studies on Innovation and Competition

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Access to Non-Summary Clinical Trial Data for Research Purposes Under EU Law

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I dedicate this work to all individuals volunteering as clinical trial subjects.

Preface

Access to clinical trial data has been subject to a long-standing policy, legislative and general public debate. Notwithstanding potential benefits for medical research and drug development, many jurisdictions have struggled to implement and enforce legal rules governing clinical trial data accessibility even at the summary results level. Policy initiatives have been strongly opposed by research-based drug companies arguing that mandatory data disclosure impedes their innovation incentives.

Conventionally, policymakers approached access to clinical trial data from the perspective of transparency and research ethics. This study offers a complementary view and considers access to individual patient-level trial data for secondary analysis as a matter of research and innovation policy. Such an approach appears to be particularly relevant against the backdrop of a data-driven economy where digital data is acknowledged as a valuable economic resource.

Overall, the study seeks to define how the rules of access to de-identified individual patient-level data should be designed to reconcile the policy objectives of leveraging research potential of data through secondary analysis, on the one hand, and protecting economic incentives of research-based drug companies, on the other hand.

Munich, Germany — Daria Kim

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Contents

Abbreviations

art/arts	Article/articles
ATC	Anatomical Therapeutic Chemical
CCI	Commercially Confidential Information
CFR	The Charter of Fundamental Rights
CHMP	Committee for Medicinal Products for Human Use
CIOMS	The Council for International Organizations of Medical Sciences
CJEU	The Court of Justice of the European Union
COM	Communication
CONSORT	Consolidated Standards of Reporting Trials
CSDR	Clinical Study Data Request
CSR	Clinical Study Report
Dir	Directive
e.g.	*exempli gratia*/for example
EC	The European Commission
EFPIA	The European Federation of Pharmaceutical Industries and Associations
EMA	The European Medicines Agency
EPO	The European Patent Office
et al.	*et alii* (*et aliae*)/and others
EU	The European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
ff	*folio*/and the following
FOIA	Freedom of Information Act
FTA	Free Trade Agreement
GCP	Good Clinical Practice
GDPR	The General Data Protection Regulation
GRADE	Grades of Recommendation, Assessment, Development, and Evaluation
GSK	GlaxoSmithKline
i.e.	*id est*/that is to say
ibid	*ibidem*/in the same place

ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMJE	The International Committee of Medical Journal Editors
IFPAM	The International Federation of Pharmaceutical Manufacturers and Associations
IP	Intellectual Property
IPD	Individual Patient Data
n/nn	Footnote/footnotes
NBER	The National Bureau of Economic Research
NCE	New Chemical Entity
NDA	New Drug Application
OECD	The Organisation for Economic Co-operation and Development
p/pp	Page/pages
para/paras	Paragraph/paragraphs
PhRMA	The Pharmaceutical Research and Manufacturers of America
PUMA	Paediatric Use Marketing Authorisation
R&D	Research and Development
RCT	Randomised Clinical Trial
REACH	The EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
Reg	Regulation
RTLA	Reach Through License Agreement
SPC	Supplementary Protection Certificate
SUSAR	Suspected Unexpected Serious Adverse Reactions
SWD	Staff Working Document
TBA	Technical Board of Appeal
TFEU	The Treaty on the Functioning of the European Union
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
UNDP	The United Nations Development Programme
US	The United States of America
USFDA	The Food and Drug Administration of the United States of America
vol	Volume
WHO	The World Health Organization
WIPO	The World Intellectual Property Organization
WTO	The World Trade Organization