Volume 2, No. 4 | July–August 2019

The Journal of Robotics, Artificial Intelligence & Law

Editor's Note: Big Data
Steven A. Meyerowitz

Big Data, Bigger Risk: Recognizing and Managing the Perils of Using Algorithms in Recruiting and Hiring
Mark J. Girouard

Artificial Intelligence and Associated Clinical Data Privacy Considerations
James A. Sherer, Taylor M. Hoffman, and Emily R. Fedeles

Risk and Opportunity with the Industrial Internet of Things
David T. Doot, Steven A. Cash, and James B. Blackburn, IV

The Robo-Criminal
Nina Scholten

AI and Image Recognition: The Next Generation Brand Protection?
Ronda Majure

Everything Is Not *Terminator:* Helping AI to Comply with the Federal Trade Commission Act
John Frank Weaver

fastcase FULL COURT PRESS

RAIL
The Journal of Robotics, Artificial Intelligence & Law
Volume 2, No. 4 | July–August 2019

231 **Editor's Note: Big Data**
Steven A. Meyerowitz

235 **Big Data, Bigger Risk: Recognizing and Managing the Perils of Using Algorithms in Recruiting and Hiring**
Mark J. Girouard

243 **Artificial Intelligence and Associated Clinical Data Privacy Considerations**
James A. Sherer, Taylor M. Hoffman, and Emily R. Fedeles

257 **Risk and Opportunity with the Industrial Internet of Things**
David T. Doot, Steven A. Cash, and James B. Blackburn, IV

263 **The Robo-Criminal**
Nina Scholten

285 **AI and Image Recognition: The Next Generation Brand Protection?**
Ronda Majure

291 **Everything Is Not *Terminator:* Helping AI to Comply with the Federal Trade Commission Act**
John Frank Weaver

EDITOR-IN-CHIEF

Steven A. Meyerowitz
President, Meyerowitz Communications Inc.

EDITOR

Victoria Prussen Spears
Senior Vice President, Meyerowitz Communications Inc.

BOARD OF EDITORS

Miranda Cole
Partner, Covington & Burling LLP

Kathryn DeBord
Partner & Chief Innovation Officer, Bryan Cave LLP

Melody Drummond Hansen
Partner, O'Melveny & Myers LLP

Paul B. Keller
Partner, Norton Rose Fulbright US LLP

Garry G. Mathiason
Shareholder, Littler Mendelson P.C.

Elaine D. Solomon
Partner, Blank Rome LLP

Linda J. Thayer
Partner, Finnegan, Henderson, Farabow, Garrett & Dunner LLP

Mercedes K. Tunstall
Partner, Pillsbury Winthrop Shaw Pittman LLP

Edward J. Walters
Chief Executive Officer, Fastcase Inc.

John Frank Weaver
Attorney, McLane Middleton, Professional Association

THE JOURNAL OF ROBOTICS, ARTIFICIAL INTELLIGENCE & LAW (ISSN 2575-5633 (print) /ISSN 2575-5617 (online) at $495.00 annually is published six times per year by Full Court Press, a Fastcase, Inc., imprint. Copyright 2019 Fastcase, Inc. No part of this journal may be reproduced in any form—by microfilm, xerography, or otherwise—or incorporated into any information retrieval system without the written permission of the copyright owner. For customer support, please contact Fastcase, Inc., 711 D St. NW, Suite 200, Washington, D.C. 20004, 202.999.4777 (phone), 202.521.3462 (fax), or email customer service at support@fastcase.com.

Publishing Staff
Publisher: Morgan Morrissette Wright
Journal Designer: Sharon D. Ray
Cover Art Design: Juan Bustamante

Cite this publication as:

The Journal of Robotics, Artificial Intelligence & Law (Fastcase)

This publication is sold with the understanding that the publisher is not engaged in rendering legal, accounting, or other professional services. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

Copyright © 2019 Full Court Press, an imprint of Fastcase, Inc.

All Rights Reserved.

A Full Court Press, Fastcase, Inc., Publication

Editorial Office

711 D St. NW, Suite 200, Washington, D.C. 20004
https://www.fastcase.com/

POSTMASTER: Send address changes to THE JOURNAL OF ROBOTICS, ARTIFICIAL INTELLIGENCE & LAW, 711 D St. NW, Suite 200, Washington, D.C. 20004.

Articles and Submissions

Direct editorial inquires and send material for publication to:

Steven A. Meyerowitz, Editor-in-Chief, Meyerowitz Communications Inc., 26910 Grand Central Parkway, #18R, Floral Park, NY 11005, smeyerowitz@meyerowitzcommunications.com, 646.539.8300.

Material for publication is welcomed—articles, decisions, or other items of interest to attorneys and law firms, in-house counsel, corporate compliance officers, government agencies and their counsel, senior business executives, scientists, engineers, and anyone interested in the law governing artificial intelligence and robotics. This publication is designed to be accurate and authoritative, but neither the publisher nor the authors are rendering legal, accounting, or other professional services in this publication. If legal or other expert advice is desired, retain the services of an appropriate professional. The articles and columns reflect only the present considerations and views of the authors and do not necessarily reflect those of the firms or organizations with which they are affiliated, any of the former or present clients of the authors or their firms or organizations, or the editors or publisher.

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the Editorial Content appearing in these volumes or reprint permission, please call:

Morgan Morrissette Wright, Publisher, Full Court Press at mwright@fastcase.com or at 202.999.4878

For questions or Sales and Customer Service:

Customer Service
Available 8am–8pm Eastern Time
866.773.2782 (phone)
support@fastcase.com (email)

Sales
202.999.4777 (phone)
sales@fastcase.com (email)
ISSN 2575-5633 (print)
ISSN 2575-5617 (online)

Artificial Intelligence and Associated Clinical Data Privacy Considerations

James A. Sherer, Taylor M. Hoffman, and Emily R. Fedeles*

The utilization of artificial intelligence practices within clinical trials is a near inevitability, making the privacy concerns more a matter of "when," not "if." To illuminate the issue, the authors of this article examine a hypothetical instance in which data is generated by a Swiss company through a clinical trial process, and such clinical trial data is subsequently considered as the underpinning data to develop new drugs and medical practices.

With the advent of advanced analytics and stronger forms of artificial intelligence ("AI"), there have been many intersections between new technology, opportunities for greater collaboration, and advances in instrumentation and practice within the clinical trial space.[1] Some of these advances have come with calls to augment (or even replace) the traditional randomized clinical trial format with information contained within existing or prospective databases,[2] while others have long warned of AI's limitations while raising ethical concerns.[3]

Regardless, however, of how AI affects the actual process of clinical trials, data compiled or generated from the clinical trial process is bound to feed new AI models of increasing efficacy and complexity.[4] AI works best when it begins with real-world data,[5] and AI applications are eager for data that provides efficient insight into "what is happening in the world" as well as data that suggests "what is likely to happen."[6] In sum, the promise of what AI and similar advanced analytics can do with clean clinical results is driving even more trials and data collection efforts.[7] While these activities carry with it incredible promise for future medical advances, there are very real legal and privacy concerns associated with the collection, processing, and use of the truly valuable information: that is personal, sensitive data that may be generated through the clinical data process. And while borders should perhaps not matter when it comes to matters of life or death and attendant medical advances[8] and governments are aware of that issue,[9] clinical trial

Robotics, Artificial Intelligence & Law / July–August 2019, Vol. 2, No. 4, pp. 243–256.
© 2019 Full Court Press. All rights reserved.
ISSN 2575-5633 (print) /ISSN 2575-5617 (online)

organizations must take into account the present-day privacy laws that impact data generation and use.

In this article, we examine a hypothetical instance in which data is generated by a Swiss company ("SwissCo") through a clinical trial process, and such clinical trial data ("Swiss Data") is subsequently considered as the underpinning data to develop new drugs and medical practices. As in real-life instances,[10] SwissCo prefers not to limit its analysis to the data it collects as part of its clinical trial; in addition to utilizing certain publicly available data,[11] SwissCo will also license data from its partners ("Partner Data"). Hypothetical SwissCo may also use sale or licensing agreements to pass that data along to certain affiliates, which might impact the privacy analysis.[12]

Swiss Human Research Act

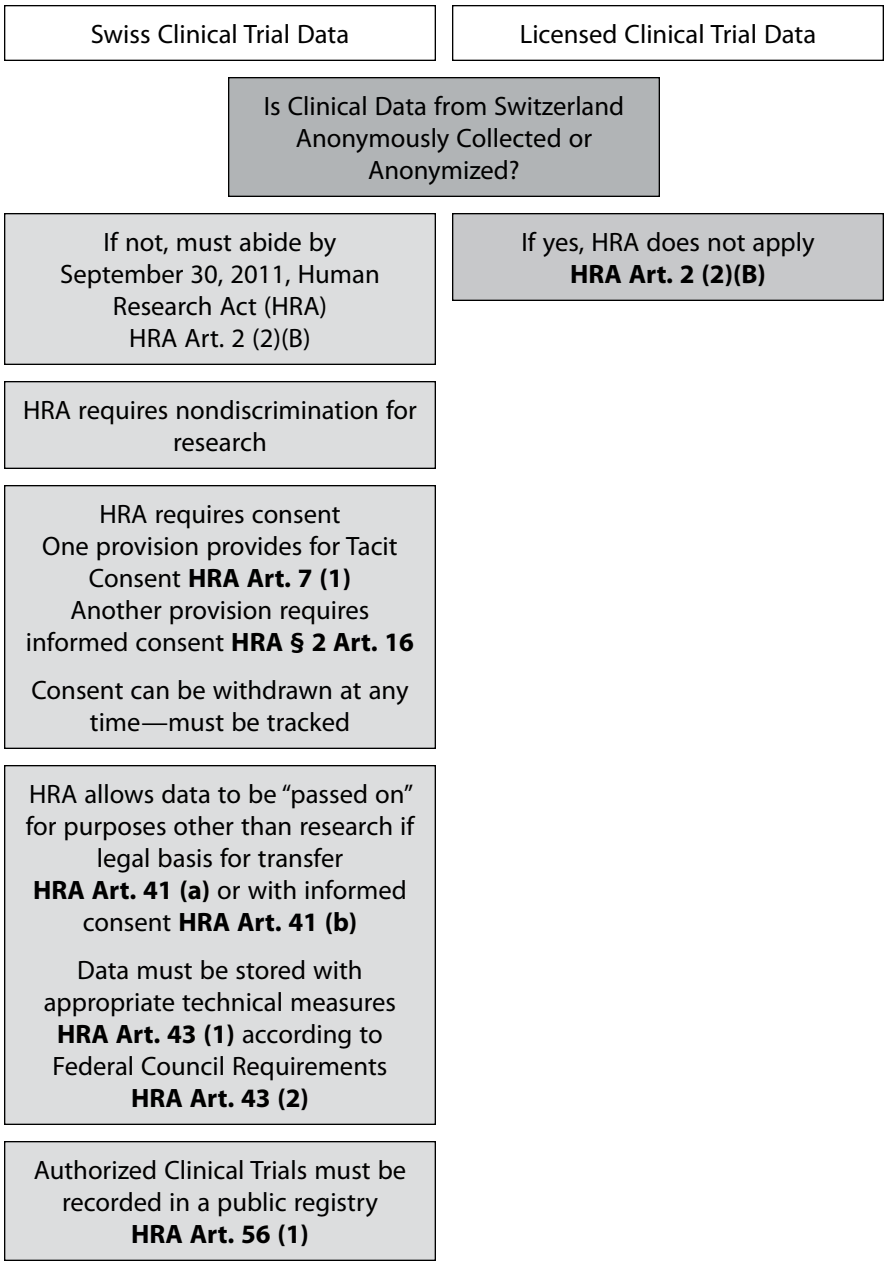
The threshold inquiry begins with clinical trial data as a more sensitive form of personally identifiable data; whether Swiss Data as well as any Partner Data would be collected in Switzerland ("Swiss Partner Data"); and whether the data are anonymously collected and/or anonymized. If the Swiss Data or Swiss Partner Data are either anonymously collected and/or anonymized, then the first point of scrutiny—the Swiss Human Research Act or "HRA"[13]—does not apply.

If the Swiss Data or Swiss Partner Data are *not* anonymously collected and/or anonymized, then the HRA does apply, and carries with it several requirements, including nondiscrimination during the research process, certain types of consent, and the ability to "pass on" the data for non-research purposes (e.g., an affiliate of SwissCo or other potential licensee) (*See* Figure 1). An affiliate's use of the data sets in this instance should include some due diligence to confirm the way the Swiss Data was generated and stored, as well as how consent was collected and maintained; likewise, an affiliate or licensee should also review SwissCo's own documentation and contractual provisions associated with SwissCo's licensing of Partner Data subject to the HRA.

Practice Point Considerations

- Is anonymous or anonymized data sufficient for SwissCo's or an affiliate's use?

Figure 1


Swiss Clinical Trial Data
Licensed Clinical Trial Data
Is Clinical Data from Switzerland Anonymously Collected or Anonymized?
If not, must abide by September 30, 2011, Human Research Act (HRA) HRA Art. 2 (2)(B)
If yes, HRA does not apply **HRA Art. 2 (2)(B)**
HRA requires nondiscrimination for research
HRA requires consent One provision provides for Tacit Consent **HRA Art. 7 (1)** Another provision requires informed consent **HRA § 2 Art. 16**
Consent can be withdrawn at any time—must be tracked
HRA allows data to be "passed on" for purposes other than research if legal basis for transfer **HRA Art. 41 (a)** or with informed consent **HRA Art. 41 (b)**
Data must be stored with appropriate technical measures **HRA Art. 43 (1)** according to Federal Council Requirements **HRA Art. 43 (2)**
Authorized Clinical Trials must be recorded in a public registry **HRA Art. 56 (1)**

- Are representations that data are anonymous or anonymized sufficient?
- Would a de-identified data set be more effective?
- Would a limited data set (e.g., as defined under the HIPAA Privacy Rule[14] that excludes direct identifiers of individual or of relatives, employers, or household members of the individual) be more appropriate or effective?

Directive 2001/20/EC and Regulation EU No. 536/2014 on Clinical Trials on Medicinal Products for Human Use

If the Partner Data is not Swiss Data but was generated in the European Union, then newly generated data may be subject to Directive 2001/20/EC (the "2001 Directive") or Regulation EU No. 536/2014 on Clinical Trials on Medicinal Products for Human Use (Clinical Trials Regulation or "CTR"), depending on when the trial occurred. SwissCo should consider the provenance of such data under the 2001 Directive, as the Directive was implemented unevenly (it was, of course, a directive, not a regulation)—this may require a nation-by-nation review based on the data set(s) to see if the studies associated with the data were compliant when captured, and what consent was associated with such data's development.

The CTR is not slated for implementation until sometime in early or mid-2020,[15] but it contemplates additional regulatory requirements as well as certain provisions associated with clinical trials conducted outside the European Union (e.g., the Swiss Partner Data) to the extent Swiss Partner Data might be a component part of a further Partner Data study. There are certain provisions for anonymizing clinical data reports under the CTR, but no specific protections associated with that type of generated data.

Practice Point Considerations

- The considerations of anonymity and limited data set raised above would still apply in this instance.
- Differential privacy issues[16]—will a combination of any of these data sets and/or publicly available data allow for re-identification of data subjects?

- Standardization of data—what data models and metadata are used to generate these data sets, and how (and at what point) will the data be harmonized for an affiliate's use?
  - Are there licensed data models associated with the data sets that an affiliate would either license or be included as a sub-licensee of SwissCo and/or the Partner Data providers (e.g., Current Procedural Terminology ("CPT") licensing through the American Medical Association ("AMA") for system nomenclature and codes).

General Data Protection Regulation (EU) 2016/679 and the Swiss Federal Data Protection Act

The General Data Protection Regulation (EU) 2016/679 ("GDPR") focuses on Data Subject Personal Data—this may include Personal Data that could identify individuals based on limited data (pertinently site, timing, and diagnosis study data); even if data is otherwise limited or de-identified, such data may come under controls associated with the GDPR. The GDPR would apply to *Partner Data*, but the GDPR would not apply directly to *Swiss Data* collected through Swiss clinical trials that involved Swiss citizens. But Switzerland's Federal Data Protection Act ("Swiss DPA") is currently undergoing a comprehensive revision that is likely to result in an operative law that matches the protections of the GDPR but incorporates lower fines than those provided for in the GDPR. The lengthy revision process for the Swiss DPA is still underway at the time of this article's publication.

General GDPR and Swiss DPA Requirements

The GDPR and Swiss DPA apply to Swiss Data and Partner Data generally, and—with limited exceptions—require the following:

- Prior consent for personal data collection;
- Transparent, plain language regarding the collection, processing, use, and transfer of such data;
- Specific breach notification requirements;
- A right for data subjects to access their personal data;

- Rights for data subjects to correct their data;
- Rights for the data subjects to restrict their or object to their data's use;
- The right of the data subject to be forgotten; and
- Considerations regarding the portability of the data for the data subject's use on a separate platform.

These all (again) require disclosure in a manner transparent to the data subject (with an exception noted within the HRA where such disclosures might affect a study's veracity).

Note that to the extent Partner Data and Swiss Data will not fit under the criteria discussed immediately below, they will be subject to these general requirements.

Clinical Data GDPR and Swiss DPA Requirements

The GDPR (and likely, by extension, the new Swiss DPA) also notes some specific issues associated with clinical trial data, categorized as "special" for purposes of scientific or research purposes. This type of data collection and use requires explicit consent from the subject for the collection of the data, where informed consent is clear at the onset. But unlike general GDPR application, data from subjects in clinical trials in the European Union *cannot* be removed subject to an otherwise available right to erasure, and portability is unavailable as well (such an omission might—or would likely—change the outcome of a trial and could come under scrutiny as a method by which results could be intentionally modified).

Processors and Controllers

Commentators[17] note that clinical trial providers are considered both processors from a customer perspective and controllers in terms of personnel and sub-contractors.[18] If an affiliate wants to utilize Partner Data as part of its AI or algorithm development (or other product or service developments), that affiliate might be considered a controller *because* the affiliate would be determining the purpose and means of processing the personal data,[19] or *if* the affiliate is processing that data in accordance with other direction, or cross-work done on other projects or ventures. There are several

other constraints associated with the GDPR when it comes to work done as a processor, including record keeping criteria.[20] Finally, if the core activities of an affiliate (or SwissCo, depending on the Swiss DPA) involve "regular and systematic monitoring of data subjects on a large scale" (that is, the core activities of the organization deal with personal data usage) the organization may need to[21] designate a semi-independent Data Protection Officer.[22]

Data Transfer Under the GDPR and (Likely) Swiss DPA

Of concern to potential affiliates, Swiss Data and Partner Data likely need to be transferred to the possession, custody, or control of such an affiliate for utilization—even if such data arguably remains housed according to data localization principles in Switzerland. Such transfers are normally allowed when the receiving organization or country provides an "adequate" level of protection for the covered personal data. But if an affiliate is located in a jurisdiction not in harmony with GDPR-type data protections (e.g., the United States), an affiliate would likely need to utilize one of the following given the location:

- Standard Data Protection Contractual Clauses adopted by the Commission according to the related GDPR examination procedure.[23]
- An Approved Code of Conduct[24] together with binding and enforceable commitments of the controller or processor in the third country to apply the appropriate safeguards, including about data subjects' rights.
- An Approved Certification Mechanism[25] combined with binding, enforceable commitments of the controller or processor for appropriate safeguards, including those for data subjects' rights.
- There may be an opportunity for a derogation or exception to the GDPR transfer requirements if the data subjects in the Swiss Data and Partner Data studies have explicitly consented to such (proposed) transfer, after being fully informed of the risks of such transfers due to the lack of an adequacy decision and appropriate safeguards associated with the United States.

Additional Considerations

Other issues associated with potential combinations of data and the fact pattern-presented detail include the following items.

General Re-Identification and/or Differential Privacy Considerations from Combining Data Sets

Combinatory data sets might include (and are certainly not limited to) the following:

- Public epidemiology data;
- Insurance carrier data;
- Other claims data;
- Absenteeism data;
- Treating physician data;
- Other available general market data; and
- Consultant data overlays.

While any individual data set might qualify as anonymous, anonymized, de-identified, or limited, such data sources may produce identifiable individuals when combined. Working Party 29 ("WP29") Guidance Guidelines on Automated individual decision-making and Profiling for the purposes of the GDPR specifically notes this, stating that anonymization is the preferred solution once the purpose of the research can be achieved without the processing of personal data.[26]

Licensing, Use, Protection, and Intellectual Property Development Issues

These issues may arise with the same (and other) data sources listed above, including clinical patient-specific data (e.g., instrumentation data and related instrumentation differential diagnosis outputs). The GDPR highlights the need for safeguards in data processing activities for scientific, historical, or statistical purposes, where data minimization, anonymization, and data security are mentioned as possible safeguards to address that requirement.[27] Likewise, information governance considerations would address the contractual requirements either an affiliate or SwissCo might

have agreed to when either provisioning the Swiss Data study or utilizing Partner Data—such requirements might include specific ISO or other audit provisions for the data's use and maintenance; or even audit rights over intellectual property developed with that Data's use.

Artificial Intelligence "Black Box" Post-Analysis Audit Issues

These considerations may include historical disparate impact affecting treatment patterns that might manifest conclusions otherwise unsupported in the data (and inappropriate as carry-forward diagnostic tools or courses of care).

Likewise, data models that have likely changed over time and become relatively untrustworthy or unreliable, or less viable to support extrapolations. For example, while disease models themselves may be (relatively) static, differential diagnoses have increased their specificity. Physician, hospital, and clinical codes have likely changed over time, and this particular consideration is raised in the context above regarding the AMA's CPT. Finally, other data inputs from other AI and machine learning systems are generally immature, and the weights given these systems and certain instrumentation data and differential diagnosis outputs can vary by organization and system—leading to potentially (and wildly) inconsistent results.

Healthcare is also specifically addressed in WP29's Guidance Guidelines on Automated individual decision-making and Profiling for the purposes of the GDPR.[28] There, WP29 explains that the GDPR defines profiling in as a combination of three elements:

1. It has to be an automated form of processing;
2. It has to be carried out on personal data; and
3. The objective of the profiling must be to evaluate personal aspects about a natural person.[29]

While not addressing health outcome determinations (and associated insurance issues), the guidance covers general GDPR principles, including requiring that the processing is lawful, fair, and transparent;[30] that data has been minimized during the collection and maintenance processes;[31] and that data must be accurate and checked for accuracy throughout the entire life cycle of the data

gathering (e.g., collecting, analyzing, building profiles, and applying profiles).[32]

Note that such types of processing are available on public interest grounds,[33] but that the type of data normally included in clinical trials is "special category personal data." As a result, the trial developers as well as subsequent users of that data must confirm that the processing is not incompatible with the original purpose, that there is an identified lawful basis for the processing of the special category data, and that the data subject is informed about the processing (unless such information would undercut the viability of the study). Consent by the data subject is a factor that makes such automated decision-making available[34] but such consent may not be available in a study, especially a double-blind model, where such information could compromise the study. Further, while this type of work may already require the appointment of a Data Privacy Officer ("DPO"), the application of these types of processes, whether using sophisticated AI or more rudimentary (but still effective) analytics, may also require the performance of a related Data Protection Impact Assessment ("DPIA") as provided in the GDPR.[35]

Further Consent Issues and Cultural Competency

Consent[36] is one of the six lawful bases to process personal data under the GDPR,[37] but there are significant concerns regarding subjective abilities to provide consent in the employment context; an employee would be effectively forced to provide "consent" in exchange for keeping her job—therefore, such "consent" was inoperative. This consent issue may be even more magnified in instances where a data subject fears for her health and would "agree to anything regarding data" to participate in an experimental study potentially offering her life.[38]

Potential cultural competency implications exist due to Switzerland's relatively homogeneous population and associated immigration limits, where data sets also may be less generalizable and less effective within more diverse populations for the Swiss Data; likewise, the Partner Data, depending on its provenance, could carry the same (if lessened) concerns. Finally, data gathering practices may require certain cultural approaches both to incorporate appropriately diverse data as well as refine the method by which consent is procured.[39]

Conclusion

As discussed in this article,[40] the utilization of AI practices within clinical trials is a near inevitability, making the concerns covered more a matter of "when," not "if." This use may ultimately center on three primary applications:

- Patient Recruitment;
- Clinical Trial Design; and
- Clinical Trial Optimization.[41]

For patient recruitment, consent and cultural competency may loom large initially, but an approach that properly addresses these issues on a fundamental level is much more likely to serve as a solid foundation for the subsequent issues. Patient recruitment will also lean heavily on the GDPR and Swiss DPA requirements for prior consent and plain language. Clinical trial design is perhaps the most critical piece for the majority of the privacy concerns (excepting the foundational permission to use the data addressed in patient recruitment), as it embodies the requirements for privacy by design found throughout the GDPR. In the process of clinical trial design, decisions regarding anonymous or clinical data utilization and sourcing arise, as do the mechanics of how data is input and exported, how it can be standardized or staged, and how combinatory data sources can help the process without running afoul of differential privacy considerations. Finally, clinical trial optimization may, on its face, be a more free-form use of AI that ultimately implicates privacy considerations the least. But the manner in which some clinical trial optimization practices work (e.g., dashboards that seek to "identify key markers that tend to correlate with patient disengagement from research studies"[42] in an effort to keep clinical trials viable) also have potential privacy effects whose considerations are novel, in part because the practices themselves are brand new.

Notes

* James A. Sherer (jsherer@bakerlaw.com) is a partner at and chair of the Information Governance Team at BakerHostetler. Taylor M. Hoffman (taylor_hoffman@swissre.com) is senior vice president and global head of eDiscovery at Swiss Re. Emily R. Fedeles (efedeles@bakerlaw.com) is an

associate in the E-DAM and Privacy Groups at BakerHostetler. This article was presented as part of the proceedings of the 2018 Capstone Legal Conference on E-Discovery National Law School of India University, Bangalore, and Kathmandu National Law College Lecture Series.

1. Guogen Shan et al., *Statistical advances in clinical trials and clinical research.* Alzheimer's & Dementia: Translational Research & Clinical Interventions (2018).

2. Mark Terry, *Artificial Intelligence is the Buzz in Clinical Trials,* BioSpace (Apr. 26, 2018). (https://www.biospace.com/article/artificial-intelligence-is-the-buzz-in-clinical-trials/).

3. David P. Byar, *Why data bases should not replace randomized clinical trials,* Biometrics (1980): 337-342; *see also* Danton S. Char et al., *Implementing Machine Learning in Health Care—Addressing Ethical Challenges,* N. Engl. J. Med. 378:981-983 (2018).

4. CB Insights, *The Future of Clinical Trials: How AI & Big Tech Could Make Drug Development Cheaper, Faster, & More Effective,* Research Briefs (Aug. 7, 2018). (https://www.cbinsights.com/research/clinical-trials-ai-tech-disruption/).

5. James A. Sherer, *When is a Chair not a Chair? Big Data Algorithms, Disparate Impact, and Considerations of Modular Programming,* DESI VII Workshop on Using Advanced Data Analysis in eDiscovery and Related Disciplines (2017); 34 C&ILJ 8 (2017).

6. Kevin Rooney, *Artificial Intelligence in Clinical Trials,* Wavelength by PRA Health Sciences (Mar. 23, 2018). (https://prahs.com/blog/2018/03/23/artificial-intelligence-in-clinical-trials/).

7. Jessica Kent, *FDA Sets Goals for Big Data, Clinical Trials, Artificial Intelligence,* Health IT Analytics—Analytics in Action News (Sept. 4, 2018). (https://healthitanalytics.com/news/fda-sets-goals-for-big-data-clinical-trials-artificial-intelligence).

8. Darrell West, *Enabling Personalized Medicine through Health Information Technology,* Center for Technology Innovation at Brookings (Jan. 28, 2011). (https://www.brookings.edu/wp-content/uploads/2016/06/0128_personalized_medicine_west.pdf).

9. European Commission, *The digital transformation of healthcare,* EC Fact Sheet (Apr. 25, 2018). (http://europa.eu/rapid/press-release_MEMO-18-3367_en.pdf).

10. Association of Clinical Research Professionals, *Clinical Trial Data Sources Poised for Spike,* Blog (Nov. 13, 2017). (https://www.acrpnet.org/2017/11/13/clinical-trial-data-sources-poised-spike/).

11. Elliott Miler, *Why Isn't There a Global Source for Clinical Trial Data?* BrackenData (Dec. 9, 2016). (https://brackendata.com/blog-posts/global-clinical-trial-database).

12. Note that this analysis of a hypothetical carries with it several caveated hypotheticals as well: the General Data Protection Regulation was enacted

as of May 2018 and has little enforcement history at the time of this article. The related Swiss Federal Data Protection Act is still undergoing revision at the time of this article, and the Regulation EU No 536/2014 on clinical trials will not enter into force until six months after the European Commission publishes notification of the confirmation of full functionality of the Clinical Trials Information System, which has not yet entered the iterative, agile development phase that necessarily predates such a confirmation.

13. September 30, 2011 Swiss Human Research Act ("HRA").

14. 45 CFR Part 160 and Subparts A and E of Part 164.

15. Gillian Rea, *The long-awaited EU clinical trial regulation,* Irish Legal News (July 13, 2018). (https://www.irishlegal.com/article/gillian-rea-the-long-awaited-eu-clinical-trial-regulation).

16. J. Sherer, J. Le & A. Taal, *Big Data Discovery, Privacy, and the Application of Differential Privacy Mechanisms,* ICAIL 2015 Workshop on Using Machine Learning and Other Advanced Techniques to Address Legal Problems in E-Discovery and Information Governance (DESI VI Workshop); 32 C&ILJ 7 (2015).

17. As noted above, the May 2018 implementation of the GDPR has not yet created an enforcement history.

18. Greg Gogates, *How Does GDPR Affect Clinical Trials?* Applied Clinical Trials (Apr. 6, 2018). (http://www.appliedclinicaltrialsonline.com/how-does-gdpr-affect-clinical-trials).

19. GDPR Art. 4.

20. GDPR Art. 30.

21. Will likely be required to.

22. GDPR Art. 37.

23. GDPR Art. 93(2).

24. GDPR Art. 40.

25. GDPR Art. 42.

26. WP 251 Rev. 01 (Feb. 6, 2018).

27. *See* Recital 156. The processing of personal data for scientific purposes should also comply with other relevant legislation such as on clinical trials; mentioning Regulation (EU) No. 2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.

28. WP 251 Rev. 01 (Feb. 6, 2018).

29. GDPR Art. 4(4).

30. GDPR Art. 5(1)(a).

31. GDPR Art. 5(1)(c).

32. GDPR Art. 5(1)(d).

33. GDPR Art. 6(1)(d).

34. Art. 22(4) referencing Art. 9(2)(a).

35. GDPR Art. 35(3).

36. GDPR Art. 4(1).

37. GDPR Art. 9.

38. *See* WP29 Opinion 15/2011 on the definition of consent (WP187), p. 12.

39. Jane Otado et al., Culturally Competent Strategies for Recruitment and Retention of African American Populations into Clinical Trials, Clin Transl Sci. 8(5): 460–466 (Oct. 2015). (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4626379/).

40. CB Insights, *The Future of Clinical Trials: How AI & Big Tech Could Make Drug Development Cheaper, Faster, & More Effective,* Research Briefs (Aug. 7, 2018). (https://www.cbinsights.com/research/clinical-trials-ai-tech-disruption/).

41. Kumba Sennaqar, *AI and Machine Learning for Clinical Trials—Examining 3 Current Applications,* TechEmergence (Sept. 26, 2018). (https://www.techemergence.com/ai-machine-learning-clinical-trials-examining-x-current-applications/).

42. *Id.*