



AI, ML & BEYOND: MEDICAL DEVICE REGULATIONS FOR THE 21ST CENTURY

ASHOK G.V.
FACTUM LAW



FACTUM LAW

CHALLENGES

- Tech and Legal Evolution matching pace
- The Drugs and Cosmetics Act, 1940 v. Medical Device Rules, 2017
- Software per se v. Combination of Hardware and Software
- Lack of multi-disciplinary approach
- Dynamic Exercise not static
- Method to the madness v. outcomes

ITM-IEC BIOETHICS





Landscape of regulations

- Data Ethics
 - Representation/Diverse and Inclusive?
 - Class
 - Gender
 - Race
 - Data Privacy
- Contract Law
 - Informed Consent
 - Undue Influence



Landscape of regulations (Contd.)

- Human Rights
 - Article 14 of the Constitution
 - Article 21 of the Constitution
- Tech Perspectives
- Consumer Protection Jurisprudence
 - Standards of Informed Consent
 - “Full Weight of Information”



Determining the Ethics of the Research

- Ethics of the Objective
- Ethics of the Methods
- Machinery: Clinical Trial Agreement & Informed Consent Forms



IITM-IEC BIOETHICS



Establishing Safety and Efficacy

- Synthetic Data for Ground Truthing
- Appetite for Data v. Individual Consent
- Benchmarking Device: Certified Specialist Criterion
 - Fixing Liability
 - Autonomy v. Agency

Informed Consent Challenges

- “Full Weight of Information”
 - Alternative Treatment
 - Risks
 - Benefits
- Blackbox predicament
- Full weight of information given to the patient?



The risk of 1984

- Assessment of Mental Health
- Lifestyle modification apps
- Who to treat and who not to treat?
- Influence of the choice of treatment





Governance Framework

- Market and Industry Surveillance
- Agile/ Adaptive
- Flexible: Systems of Waivers
- Intellectual Property Considerations v. Privacy Concerns



Governance Framework

- Diverse Stakeholders Multi-Disciplinary Approach.
- Proactive: Identify data privacy concerns and ethics issues ahead of harm.
- Responsive and Consultative
- Social Benefits and Public Health and Well being
- Primacy of individual

References

- “The Ethics of AI in Biomedical Research, Patient Care, and Public Health” by Alessandro Blasimme and Effy Vayena Oxford Handbook of Ethics of AI (OXFORD HANDBOOKS SERIES) (p. 703). Oxford University Press. Kindle Edition.
- *Samira Kohli v. Prabha Manchanda* reported in (2008) 2 SCC 1
- “Will Synthetic Data Introduce Ethical Challenges for ML Engineers?” by Gilad David Mayan, published in “Towards Data Sciences” July, 9, 2022;
<https://towardsdatascience.com/will-synthetic-data-introduce-ethical-challenges-for-ml-engineers-b2608139d27f>
- Medical Device Rules, 2017

References (Contd.)

- *Sheela Srivastava and Ors v. Rajiv Gandhi Cancer Institute and Research Centre and Ors* in 1st Appeal No. 1009/2014
- *Montgomery v. Lanark Shy* [2015 UK SC 11] Please see paragraph 87 to 89 at ink page 29 of Volume 1 of List of Authorities
- Volume 1, Chitty on Contract, 33rd edition, at page 799
- UDHR Principles for Protection of Persons with Mental Illness and the Improvement of Mental Health Care

Thank you

– ashok@factumindia.law

– 9986328007

IITM-IEC BIOETHICS

