



Q&A to IFPMA Webinar on Data Ethics Principles

Introduction

eBIC's mission is to ensure IFPMA's members are up-to-date on current developments and emerging areas of interest. The IFPMA Webinar on Data Ethics Principles is a real-time opportunity session to exchange views on the newly created [IFPMA Data Ethics Principles](#) (published in June 2021). As an outcome of the webinar, the group agreed to generate a Q&A document providing support to members when dealing with the Data Ethics Principles.

Panelists/subject matter experts:

- Sobia Akram, Novo Nordisk
- Anna Dolinsky, Novo Nordisk
- John Olwal, Novartis
- Uma Swaminathan, GSK
- Jeffrey Scott, Pfizer

Questions & Answers

1. Why focus on Data Ethics?

The Data Ethics principles are intended to help the pharmaceutical industry use data responsibly and sustainably and to maintain trust with patients and society, as trust in this space can easily be lost because of its complex nature and opaqueness of the activities of even well-intentioned actors.

Data is at the heart of innovation and represents profound opportunities in R&D, commercialization and beyond. There is also an increasing scrutiny and enforcement about data use. The field is moving rather fast. The reason to act now is to reinforce the trust in our industry, be at the forefront in this space and influence the regulatory framework development.

2. What are the Data Ethics principles?

Principles that enable responsible and sustainable use of data while keeping the individual at the center and recognizing the important benefits of the data for society and science in general. Data includes all types of data collected, analyzed, stored, shared, and otherwise processed by pharmaceutical companies.

3. Is there one principle that is more important than another?

Every principle is equally important. Depending on where the company is in its data journey, one principle can be more important for that company in a given moment.

4. How to embed and operationalize Data Ethics principles within the organization?

This is a challenging component. Based on the level and maturity in the journey of integrating data ethics principles, it is important to educate and foster Data Ethics literacy and build a Data Ethics culture. This is done through raising awareness, offering training and capability building and communicating company's position on Data Ethics to third parties. It is also important to embed Data Ethics into the company ways of working and its governance. This is done through establishing ownership and accountability with business data owners, embedding Data Ethics into overall enterprise data policies and viewing ethical data as an asset. The third important element is the need to enforce data ethics risk assessment and controls. This can be achieved through extended monitoring beyond standard controls to cover the full spectrum of the 7 IFPMA Data Ethics principles and the regular execution of self-assessments (e.g., through internal audit).

5. Who should own the project of implementing Data Ethics within the organization? Compliance or another function?

It is up to every organization to perform this assessment and place every component where it belongs for them. It needs to be done through co-creation and partnership within the organization. Organization may consider developing a RACI chart at the beginning to establish clarity.

6. Do the principles apply only to companies or also to industry associations?

Yes. The principles apply also to associations, as associations and companies are important components of overall health systems.

7. What are some of the biggest challenges for the operationalization of the Data Ethics principles?

The biggest challenge lies most likely in capability. Data Ethics is a multidisciplinary question. Debating components and agreeing on position can be done through a multidisciplinary committee that is able to approach and enforce these disciplines and integrate them into the operations over a period of time.

8. What to do with the data once the project is completed?

This is tied to the data life cycle management. The organization must think about the data life cycle and define re-usability and data sharing going forward.

9. How to ensure diversity and inclusion across all parts of Data Ethics?

It is more than the specific case of ensuring diversity in clinical trials. It is also diversity in the skillsets and the backgrounds of the decision makers around data collection and data use. We come with biases that dictate how we decide which data should be collected and how we interpret them. Another piece that will need to be addressed in more detail through the upcoming AI principles is: how to actually build in controls both during the design, the build and the testing and the ongoing operations of your AI to prevent that kind of bias.

10. What can pharma companies do to help the society in the context of COVID-19?

COVID-19 has been in many aspects an eye opener with many lessons learnt. It pushed the industry to revolutionize and adapt quickly to the new situation that led to innovative ways and not only protecting the data but also doing it in a sustainable and pragmatic way. It is a journey and IFPMA

helps us on this way of cross-fertilization of best practices. Considering there is no boundary for information, it will enhance the transparency of the industry related to what they are doing with data. This goes in line with the societal expectations. Previous boundaries have been disrupted by technology. Through transparency, companies can enable data transparency in a way that benefits society and they can take the advantage of globally available information and use it in research.

11. How will Data Ethics change in a block chain ecosystem in which 'people', patients own their own health data?

Many of the Data Ethics principles may be applicable in this context. Companies should implement data principles while having in mind how quickly this space may evolve in terms of technology and regulatory framework. From a societal perspective, because the way how people think about owning their data will also evolve. Our principles recognize the importance of the individual at its center and together with the societal benefits of data use and sharing and that will probably be part of the transparency efforts that the industry needs to make not only to explain how it uses the data but also how it uses the data for good.