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Position Paper

Promoting Research While Safeguarding Patient's And Public Interest

What few people know is that the initial spark of LynxCare started with Sharon Feder and Dr. Michael Victoroff, the mother of a patient and a doctor who helped her gain insights into her son's complex medical history. Over many years, Michael and Sharon helped many patients by building "patient summaries". These manually curated overviews of the patient's medical history provide transparency to all healthcare providers involved. Georges and Dries, co-founders of LynxCare, committed to helping build software that would automate that process and would help doctors gain insight in scattered, complex, medical data to accelerate patient paths to cure. This paper is addressed to all parties working in the interest of the patient. To unlock the potential in healthcare data, help patients and find new cures, but also to safeguard that this medical data does not, under any circumstances, become a commodity for trade.

Summary

Under the protection of the GDPR, the starting premise should be that RWE patient data must be freely available for scientific research to the benefit of not only researchers, but of the patients as well. LynxCare supports its healthcare and research partners in this endeavour with a model that enables a fair contribution of all parties, aligned with the patient's and public interest.

The Challenge

The healthcare landscape has become increasingly data-driven. Especially the "Real-World" patient data in hospitals is rightfully considered as fundamental for gaining new knowledge through research, which catalyses healthcare innovation. Creating ethically and legally sound models to make this data available for research directly plays into the government's intent to turn Belgium into a 'health and biotech valley' that stimulates R&D[1]. LynxCare aims to contribute to this ecosystem by taking up the pivotal role of structuring large quantities of patient data, and making them easily available for the hospital to improve quality of care, to enable research and overall to better help the patients of today and tomorrow.

> *A recent study has indicated 76% of the Belgian population is willing to share their health data with hospitals and research institutes for scientific research.*

[1] Coalition Agreement 30 September 2020, https://www.belgium.be/, p.18

Of course, this data can only be used in full compliance with the General Data Protection Regulation (GDPR). Luckily, the GDPR has provided us not only with constraints, but also with opportunities to use health data. With adequate transparency and security measures, it is possible to re-use collected health data for managing the quality of care and for performing scientific research without the need for an explicit patient consent[2] (except maybe for certain conditions where consent is a much-needed safeguard). The need for this kind of data re-use is also understood by the public. A recent study has indicated that 76% of the Belgian population is willing to share their health data with hospitals and research institutes for scientific research.[3]

The fact that a lot of data can be "unlocked" this way creates many opportunities for hospitals, clinicians and research partners. However, we should be aware that the risks of data misuse lurk around the corner as well. LynxCare's vision is that the true value of unlocking data lies in the use of that data for the benefit of patients. So, this data should not be seen as simply a commodity or an object of trade. For this reason, a framework guaranteeing the fair use of health data, supported by a data governance structure at hospital level, is needed.

Framework for a FAIR use of Health Data

There is a distinction between having health data at your disposal on the one hand, and the efforts needed to use or "valorize" this data on the other hand. Real-World patient data is indeed necessary, but in itself insufficient or performing research. Considerable efforts by many stakeholders are needed to ensure that the data is usable for high-quality scientific research.

> *For example, hospital X has a large quantity of unstructured patient data in its electronic health records and other systems. The first step would be to define one or more research questions and define medically relevant data points. This must then be evaluated for its scientific value. Next, the data must be mined and structured into an easily usable format. This can be done manually (which would prove a very cumbersome task) or through innovative technology (like LynxCare NLP algorithm for health data). The processed data needs to be pseudonymized as much as possible, and a secure environment must be created to store the pseudonymized research data. Preferably, a dashboard or similar interface is created to give the hospital access to the structured data. A quality check on the data is also required before re-ports can be drafted. For anonymous reports to be shared with research partners, the aggregation of the data also requires an effort.*

This example doesn't even mention a lot of other intermediary steps (e.g. contracting, setting up access points, etc.) but it already shows clearly that the contributions of the hospital and its third party contractors/(sub)processors are important, time/cost consuming and require compensation to make them possible. There are basically 2 options to approach this compensation:

1

Remuneration for research efforts.

2

Remuneration for patient data.

[2] Art. 6(4), art. 6(1)(e or f) and art. 9(2)(j) GDPR.
[3] Koning Boudewijnstichting, Zorg voor je data. Informatiebrochure over gezondheidsdata, januari 2022, https://kbs-frb.be/nl.

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Approach 2 basically comes down to selling patient data and is considered both ethically and legally unacceptable for several reasons:

- doing so would turn the focus on money instead of more important aspects like upholding good research practices (incl. data protection) and advancing healthcare in the interests of patients. It would raise the issue of value transfers prohibited under anti-gift laws[4];
- given these risks, plain data monetization is not one of the justifiable purposes for which GDPR wanted to give researchers more leeway either;
- it would eventually also restrict data access to the highest bidder instead of the most promising research initiatives. This would clearly contradict the current government administration's goal to establish a level playing field for all stake-holders when it comes to secondary use of data in research[5]; and
- it could also put pressure on the current system for financing hospitals. In Bel-gium, hospitals are to a large extent subsidized by the government and it are these public resources that in part enabled the collection of patient data. It seems only logical that those data are then also made available for research in the public interest.

Approach 1 avoids these risks. Moreover, it makes sure that stakeholders are compensated based on the fair value of their (intellectual, technical or other) efforts for the research project. This enables a healthy competition between stakeholders and stimulates innovative approaches that eventually facilitate research in the interest of society, and especially the patient population. To make the remunerations for the re-search efforts more specific, there are 3 pillars on which remunerations can be based:

Cost of Hospital

- IT effort for start-up
- Goverance effort for project approval

Typically flat fees which must be market-based and substantiated by actual costs (may vary for high vs. low complexity).

Cost of Processor

- Data extraction
- Data processing
- Reporting

(License) fees which must be market-based. With LynxCare, these fees can already be paid-up via co-financing.

Cost of Analysts

- Quality control via PI, Key Opinion Leader (KOL), data manager…

Typically hourly fees, which must be market-based as well.

Note: the use of market-based fees refers to the standards in the research market and aims to avoid that these fees are used indirectly to ask a fee or premium for the medical data as such.

[4] For Belgium, see art. 10 Medicines Act; art. 38, §2 Coordinated Healthcare Professions Act.
[5] Koning Boudewijnstichting, Zorg voor je data. Informatiebrochure over gezondheidsdata, januari 2022, https://kbs-frb.be/nl.

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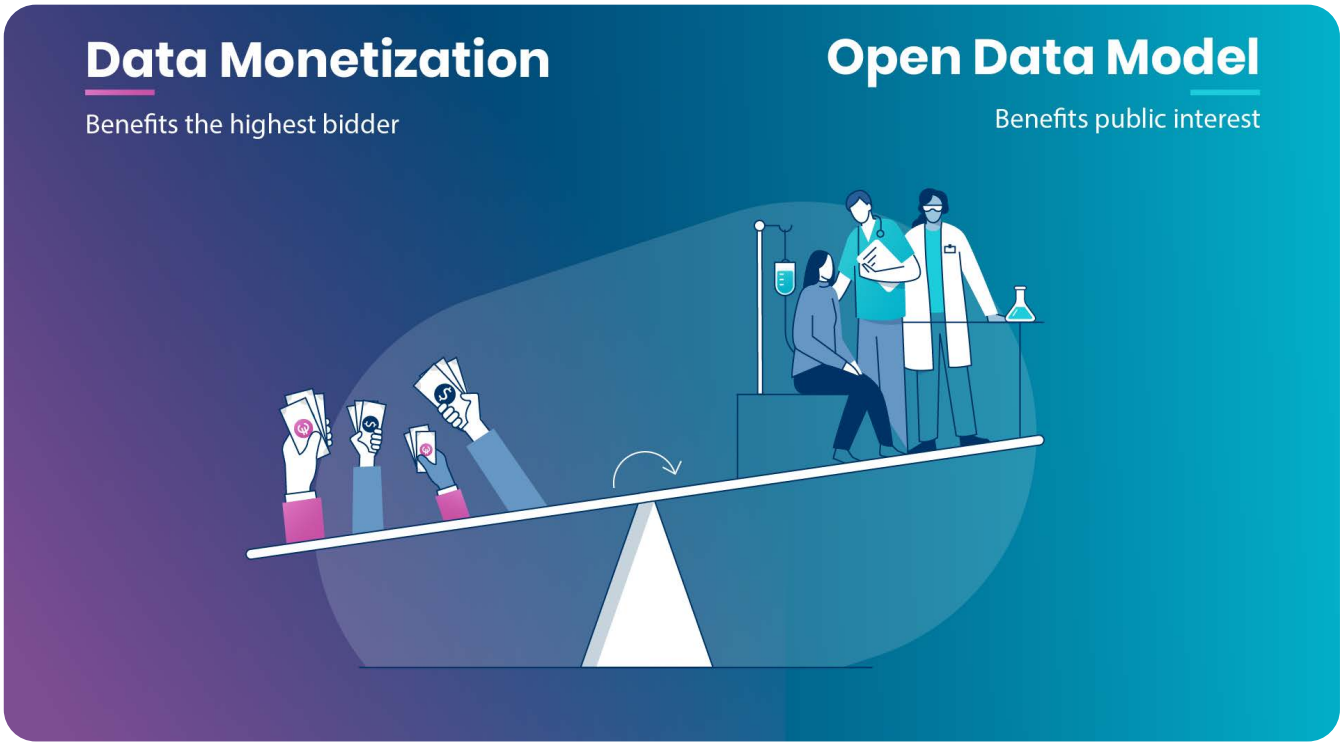
Data Governance

A clear governance structure on the hospital's side is needed to ensure research can be enabled and patient interests are safeguarded at all times. This fits perfectly in LynxCare's data protection approach, where the hospital (in collaboration with its physicians) remains legally in control, the patient's rights are safeguarded and research can be promoted.

The ideal data governance is based on the following principles:

- within the hospital, a data governance structure (e.g. data board or data com-mittee) should be in place, which acts as an ethical and quality-focused gate-keeper that decides on data use. It represents the hospital and its clinicians, while making sure that the interests of patients are taken into account;
- If any data would be used for research, the hospital's governance structure will review the research proposal and only approve it if the research questions are scientifically sound and could genuinely create healthcare benefits for the broader public. The patient should be informed about the possibility of sec-ondary data use for research, through appropriated means chosen by the hos-pital;
- any third party mining or structuring the hospital's data should do so as a (sub) processor and should comply with the hospital's instructions, thus ensur-ing the hospital's control over the data; and
- the patient's personal data can never leave the hospital's control; only statistical reports that are verified as anonymous (no personal data; only aggregated in-sights) can be shared for research in line with scientific interests. Hence, the hospital does not "sell" patient data in any way.



Get in touch with our team of clinical experts
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