MyConsent

Unlock the full potential of research data and bring consent into the digital age

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Whitepaper
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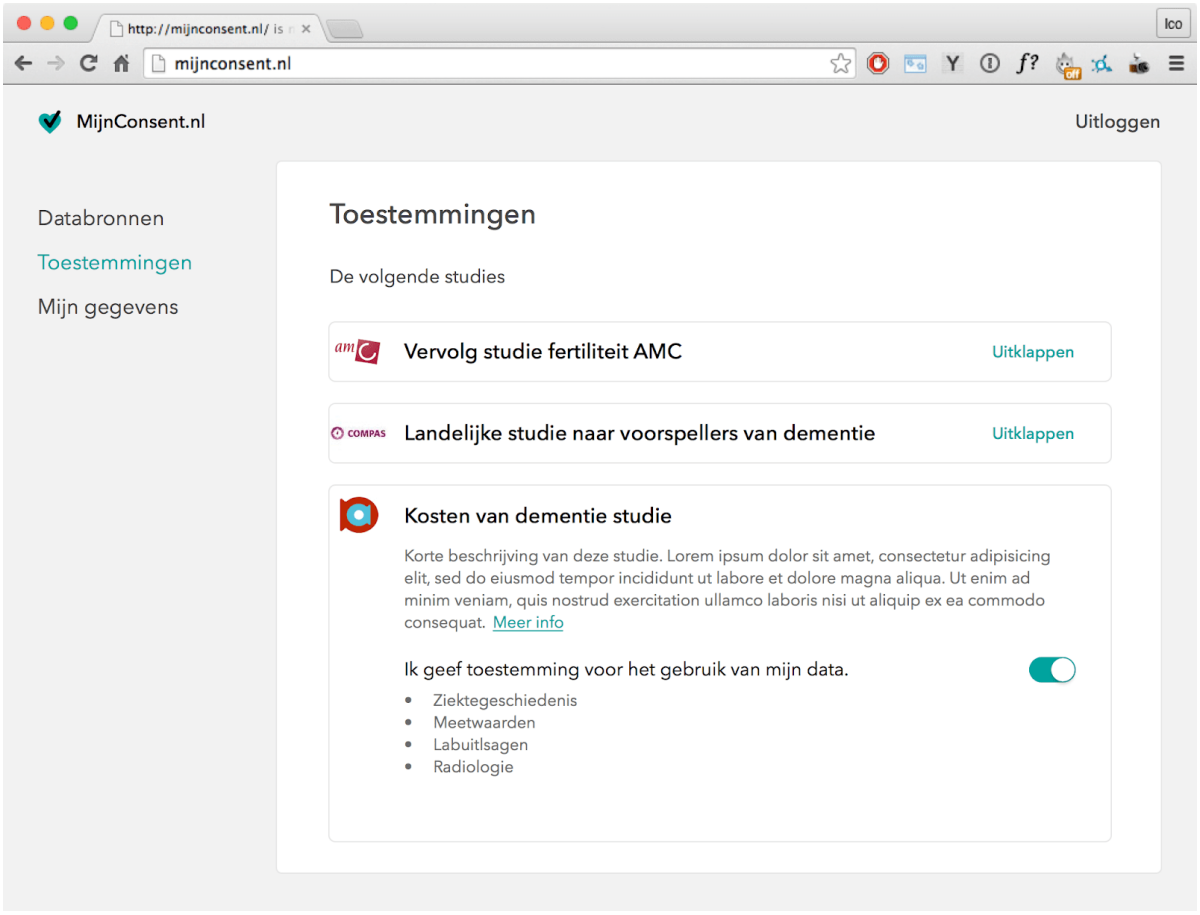
Introduction

One of the key concepts of reducing research waste optimal use of medical data and patient samples. With current and upcoming legislation, increased sensitivity and awareness is raised on *precise* rather *than* broad informed consent on the use of for example Electronic Health Record (EHR) data or biobank material. In order to optimize patients' decisions on the use of these data and material, we aim to develop MyConsent: an online platform that will revolutionize the way control over consent is managed. It offers the patient one location where consent for new and running studies can be managed. The patient is always aware how and why data and samples are being used. Additionally, the introduction of MyConsent facilitates the patient to execute his/her right to opt-out. Patient permission can no longer be assumed, as it sometimes is in the case of using EHR data or residual biosamples. Inviting patients for participation in a new study is easy and can be done without identifying the approached patients. The system removes the need for storing identifying information together with the research data. New study or biobank participants register at MyConsent.nl with a MyConsent card that creates an anonymous cryptographic link between the data source and the encrypted personal details in the MyConsent portal.

The MyConsent portal

The MyConsent portal (figure 1) offers the possibility to invite patients for new studies and ask for consent for data reuse and for linkage of various sources. E.g. linking EHR data to the Achmea Health Database for a study into healthcare costs. Because the patient is in control of personal details inthe MyConsent.nl portal, study patients can be contacted by researchers even after a long period of time has passed. People move and change phone numbers, but the portal provides one central location where a patient updates these details. This will allow researchers to stay in touch with their patients. The platform represents a pragmatic and feasible implementation of what is known as 'Dynamic Consent' (DC). Several European initiatives have investigated the use of DC and underwrite the need for such a system.

Figure 1. *The MyConsent portal: A patient friendly interface to manage consent*



Advantages of the MyConsent portal

- Researchers can obtain digital, verifiable and traceable consent for use of data
- Patients have control over usage of their data through implicit or explicit consent
- Patients can be informed of developments regarding studies they participate in
- Participants can easily be be invited for new studies and experiments

Parties involved

The initial idea for MyConsent came from Derk Arts, MD, PhD at the AMC in Amsterdam and founder of Castor EDC. He futher refined the concepts behind MyConsent with researchers in the AMC, including:

- Dr. Carrie Ris-Stalpers, coordinator Biobank Reproduction and Development, associate professor AMC-Vrouwenkliniek
- Prof. dr. Sjoerd Repping, Head of the Center for Reproductive Medicine – AMC
- Dr. mr. Corrette Ploem, lawyer in Healthcare law, dept. Social Medicine – AMC
- Prof. dr. Tessa Roseboom, Center for Reproductive Medicine – AMC
- Dr. Jörg Hamann, AMC biobank coördinator, AMC Biobank

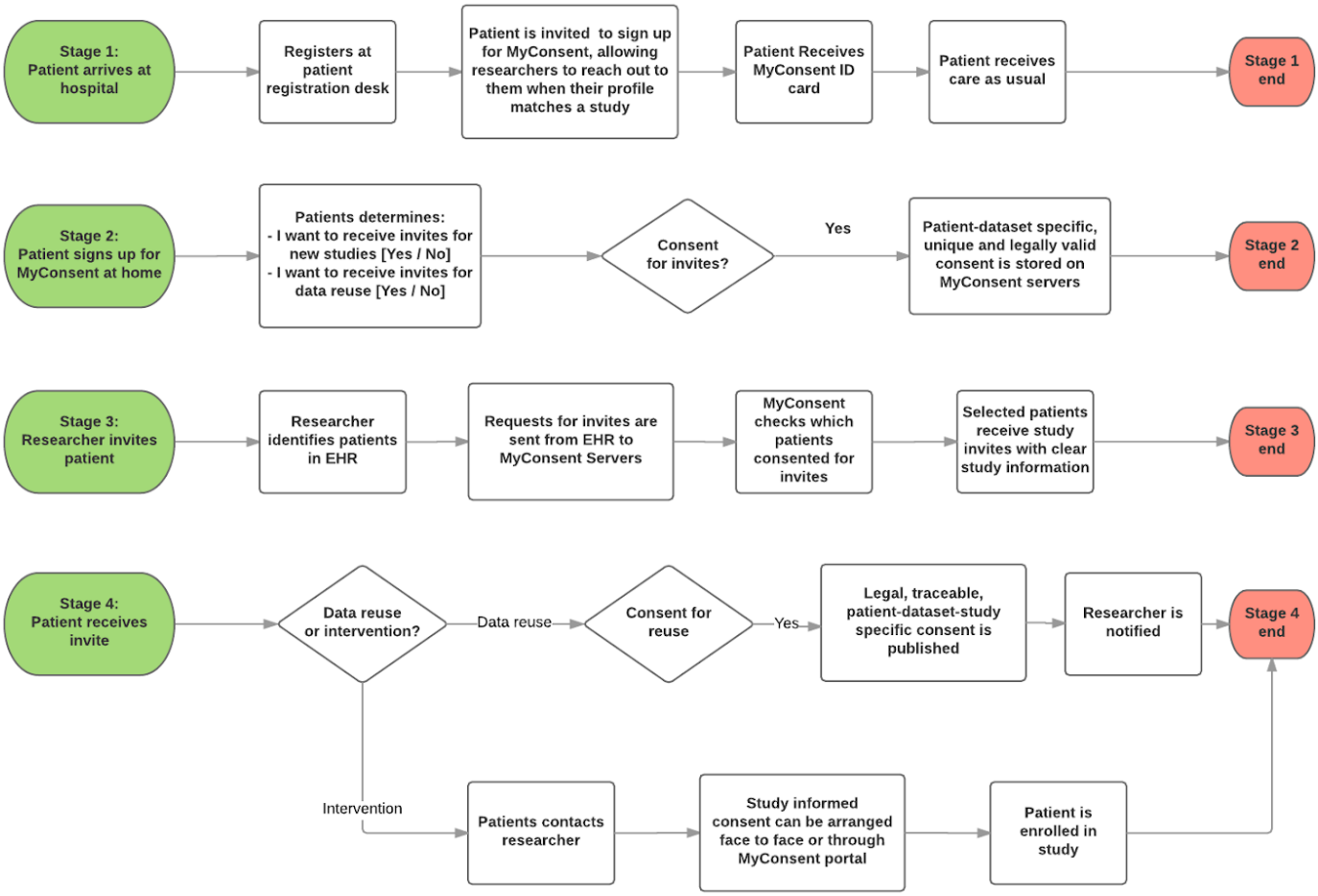
To ensure safety of the platform, Thales Nederland is involved to consult on matters related to cryptography and security. Through an awarded BBMRI voucher we are collaborating with Prof. dr. Jane Kaye, Director of the Centre for Law, Health and Emerging Technologies (HeLEX) at the University of Oxford. She is an expert on the topic of Dynamic Consent and will consult on matters regarding digital consent. Dr. Folkert Asselbergs is involved in the project as an advisor and intended pilot user of the system.

Integration possibilities

The MyConsent portal will be accompanied by web-services that can be queried by any external systems through a REST API. This will allow, among other things, a hospital EHR to identify which patients have provided consent for certain studies.

The four stages of the MyConsent process

The flowchart below depicts the four stages of the MyConsent process, from entering the hospital to providing consent for data reuse:



Current status

The MyConsent portal is currently being developed and will soon be piloted in the AMC. We are looking to secure additional funding to improve the pilot version and accelerate development. Furthermore, we are looking for additional piloting opportunities.

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