A Dynamic Digital Consent Tool using SOLID

Chang Sun, Michel Dumontier

Institute of Data Science, Faculty of Science and Engineering, Maastricht University

1 Introduction

Patient data including laboratory test data, medication and treatment data, and lifestyle information are of significant value in clinical decision-making (primary use) as well as health research (secondary use). However, using and processing these data requires a lawful basis, such as informed consent, which can be challenging to administer. Particularly, obtaining consent from numerous participants for large-scale public health research is expensive and requires significant time [1]. We propose a dynamic digital informed consent platform that can facilitate this interaction by enabling researchers to customize the purpose, period, and process of the data use, as well as comply with data privacy regulations. Using the platform, researchers can post a request for consent and patients can browse and respond to the request and grant fine-grained access to their data. We compare the proposed dynamic digital consent with traditional static consent and describe our evaluation plan with 5 privacy officers and 14 Leukemia patients in the Netherlands to test which granular level of data is more acceptable for privacy officers and patients.

2 Method

The digital consent tool is based on our previous work on TIDAL – Citizen Centric Data Platform [2] and extended to a use case for Leukemia patients to share their data with health professionals and researchers under a project called CMyGuideline [3]. The digital consent tool[1] serves as a web application using SOLID (SOcial Linked Data) technology [4], linked data (semantic web) technologies, and Data Privacy Vocabulary [5] based on EU GDPR. SOLID pods serve as personal data storage where patients can store their personal data and the researchers can store their informed consent. In our use case, a sample of patient data was prepared and stored in individual SOLID pods beforehand. The data were split into demographic, health-related, and socio-economic categories and stored in separate data files in SOLID pods. The data elements such as date of birth, weight, and glucose are linked to SNOMED CT vocabulary [6] using RDF.

To extend our original TIDAL work, we enhanced the digital consent component in TIDAL and compared it with the existing non-digital consent. We intend to test which granular level of data was more acceptable for patients. If the digital consent requests a general level of personal data such as "health-related" data, patients may be less willing to approve the consent [7]. But if the consent requests a comprehensive list of data elements at a granular level such as "Hemoglobin A1c, Low-density lipoprotein cholesterol, High-density lipoprotein cholesterol", patients may feel overwhelmed and affect their decision-making to accept or decline the consent[8]. Patients can view the published ongoing consent and make their own decisions for their data (shown in Figure 1). The consent information is retrieved directly from the researcher's solid pod and no changes and modifications are allowed after the consent is published. When they approve the consent, the patients can indicate if they would like to receive the results (i.e. publications, articles) when the study is finished.

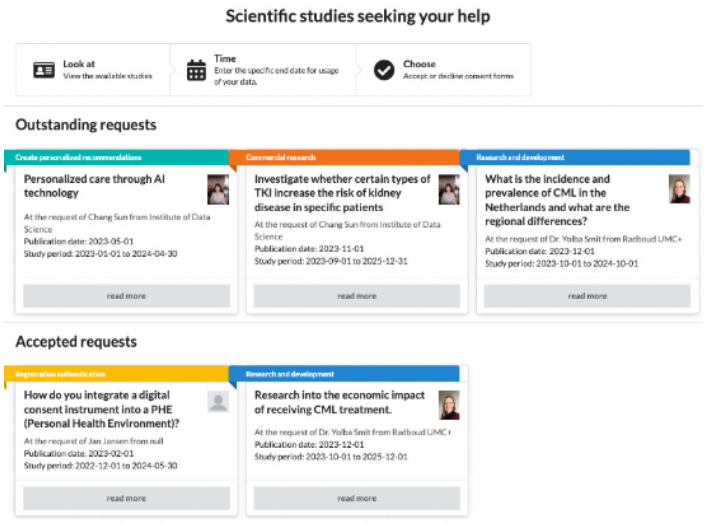

Figure 1. Published digital consent for requesting patients data

We designed the dynamic digital consent form for researchers to fill in their research purposes, consent period, requested data, planned analysis methods, and other information using Data Privacy Vocabulary which specifically captures the relevant concepts of data processing in relation to EU GDPR and compared our digital consent with the traditional static consent which was used in the CMyGuideline project to request data from leukemia patients (shown in figure 2). Dynamic consent is defined as a personalized, digital interface that directly connects participants and researchers. Researchers can dynamically create different informed consent based on their research purpose and requirements, while only participants who meet the requirements and have the required data can view and approve the consent. The dynamic digital consent covers all the elements in the existing consent document with more details and specifications. For example, the purpose category of requesting data is pre-defined and linked with GDPR defined purpose of data use. In the traditional static consent, the purpose can be described as "research", while

[1] Digital Consent Tool Web Application: https://maastrichtu-ids.github.io/CVDPrediction/dist/cmlparticipate.html

in the digital tool research can be academic research, commercial research, and non-commercial research which are specified in GDPR. This means researchers need to be more specific on their purpose of data requests using the digital tool. The same with the personal data category and data processing category, researchers need to be clear and indicate what category of personal data they are requesting and what exact data processing steps they will do (complying with GDPR). Another highlight of digital consent tools is separating requested personal data categories and particular data elements. A consent can ask for a patient's health-related data which goes to the "Personal data categories" component. This can be seen as a broad consent. From the GDPR perspective, consent should be precise and clear about what exact data variables are being requested from the individuals which is the "data element" component in the digital consent tool. Using the digital consent tool, the data elements can be linked with well-recognized terminologies or coding systems such as SNOMED CT which can match the data stored in the patients' SOLID pods.

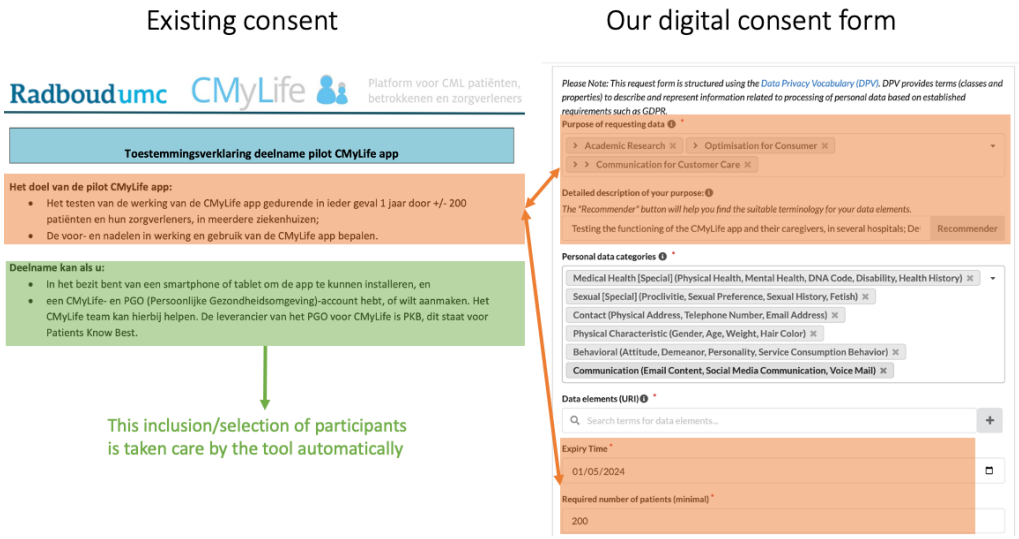

Figure 2. A part of a comparison between traditional static consent with our digital consent

3 User evaluation

We are evaluating the digital consent tool by inviting 5 data privacy officers from hospitals, clinics, and universities and 14 patients from the leukemia patients' group in the Netherlands to test the tool and conduct interviews individually. The interviewed patients are recruited from a patient group who are getting treatments at Radboud UMC and who had experience or are interested in sharing their data with health research projects. The evaluation focuses on 1) assessing how information presentation in the digital consent can impact patients' engagement and comprehension. 2) understanding patients' preferences for more flexible data-sharing options, potentially enhancing their control in data sharing, 3) understanding the impact of social influence on patients' motivation to participate in research by sharing their data.

REFERENCES

[1] *Haring, L.V., Hall, J.T., Janssen, A. et al. Developing a digital informed consent app: opportunities and challenges of a new format to inform and obtain consent in public health research. BMC Med Ethics 24, 97 (2023). https://doi.org/10.1186/s12910-023-00974-1*

[2] *Sun, Chang, Marc Gallofré Ocaña, Johan van Soest, and Michel Dumontier. "ciTIzen-centric DAta pLatform (TIDAL): Sharing distributed personal data in a privacy-preserving manner for health research." Semantic Web 14, no. 5 (2023): 977-996.*

[3] *CMyGuideline Project Website: https://www.cmylife.nl/projecten/cmyguideline access on 19 March 2024*

[4] *Sambra, Andrei Vlad, Essam Mansour, Sandro Hawke, Maged Zereba, Nicola Greco, Abdurrahman Ghanem, Dmitri Zagidulin, Ashraf Aboulnaga, and Tim Berners-Lee. "Solid: a platform for decentralized social applications based on linked data." MIT CSAIL & Qatar Computing Research Institute, Tech. Rep. (2016).*

[5] *Pandit, Harshvardhan J., et al. "Creating a vocabulary for data privacy: The first-year report of data privacy vocabularies and controls community group (DPVCG)." On the Move to Meaningful Internet Systems: OTM 2019 Conferences: Confederated International Conferences: CoopIS, ODBASE, C&TC 2019, Rhodes, Greece, October 21–25, 2019, Proceedings. Springer International Publishing, 2019.*

[6] *Donnelly, Kevin. "SNOMED-CT: The advanced terminology and coding system for eHealth." Studies in health technology and informatics 121 (2006): 279.*

[7] *Richter, G., Borzikowsky, C., Hoyer, B.F. et al. Secondary research use of personal medical data: patient attitudes towards data donation. BMC Med Ethics 22, 164 (2021). https://doi.org/10.1186/s12910-021-00728-x*

[8] *Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension-systematic review. Trials. 2021 Jan 14;22(1):57. doi: 10.1186/s13063-020-04969-w. PMID: 33446265; PMCID: PMC7807905.*