

ProSkive – Conceptual design and prototypical implementation of a platform for customizable application process management

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Research projects that are based on clinical data or biomaterial usually require an application and approval process before access is granted [1]. In most institutions, information regarding individual process steps are communicated via e-mail or paper-based. Additionally, the processes for application approval of several institutions are not harmonized. A static process which maps the steps of every medical center cannot be established and implemented in a platform. Within MIRACUM¹ as a part of the Medical Informatics Initiative [2], funded by the German Ministry for Education and Research (BMBF) [3], a customizable platform called *ProSkive* for submitting and managing applications is to be designed as an open source solution to fit this purpose.

The initial step of this process is the submission of a project proposal for data usage to request the datasets needed. This application is sent to one or several medical centers, which usually belong to hospitals. At each center, the application processing includes several steps. Once the application is submitted, it is checked for formal and content-related correctness before it is forwarded to a committee for evaluation. This may be for example a Use and Access Committee. In case of approval by all committees, further formal and legal steps are necessary before providing clinical data.

Due to the heterogeneous process structure at the individual centers, particular emphasis should be placed on individually adaptable and customizable processes. The main objective of this publication is to evaluate whether an adaptable process can be developed and implemented in form of a customizable platform. A concept of an adaptable process and results of the implementation of a first prototype are presented.

¹ Medical Informatics in Research and Care in University Medicine. <https://www.miracum.org>

The initial application approval process in the field of biobanks was adapted through the exchange with experts and implemented within a first prototype comprising a static application process [4]. The search for existing solutions to this problem yielded entirely commercial ones.

Based on the experiences and evaluations of *ProSkive Bio*, as well as expert interviews within the MIRACUM project, core elements for the application forms were detected and the application approval process was included and extended in the conceptual design of the customizable platform.

The joint exchange between the MIRACUM partners resulted in a first model of an adaptable process that is divided into several groups and ends with the release of the data or rejection of the application. Examples of these groups are the applicants, coordinators or an administrative office and an evaluation committee, while a user can be assigned to one or more groups. Cyclical or parallel processes should also be representable and configurable independently by the site and although a general process framework was defined, *ProSkive* allows for site-specific changes in the single process steps.

This first prototype covers the initial step of the designed process, which yields a first level of assistance. However, the prototype is still limited. The remaining offline parts of the approval process still have to be managed manually.

After the rollout of the prototype feedback from the partner sites was collected and analyzed. Based on this feedback, missing steps of the process were developed. In the following steps, the entire process will be gradually implemented using a feedback-driven development.

References

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