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National Trial Overview: Towards Accessible and Patient-Centered Healthcare

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Abstract. This protocol paper explores the initiative to build and implement a National Trial Overview to make clinical trials more accessible to patients and health professionals in Denmark. The paper address how a user-centered evaluation of the platform will be conducted and how the National Trial Overview can contribute to enhancing diversity, equity, and inclusion of patients and health professionals, and make access to clinical trials more patient-centered.

Keywords. Clinical trials, digital health platform, diversity, equity, inclusion, accessibility, patient-centered.

1. Introduction

The Danish healthcare system is a frontrunner in digitalization. Each individual has a unique personal identifier (a ten-digit number) which is key in accessing health data for patients and healthcare professionals (HP) through patient registries, databases, patient records, national platforms, etc. [1]. Clinical Trials (CTs) are used to test efficacy and safety of drugs and medical devices to improve the healthcare system [2].

Historically, patients have been adapting to the healthcare system, and today, CTs performed in Denmark are still system-centered rather than patient-centered; most often, patients must be at the right hospital at the right time to be recruited to participate in CTs [3]. This creates inequity in patient care in terms of diagnosis and treatment. To reduce these inequities, the healthcare system and CTs must become more patient-centered and personalized [4]. To enhance the patient-centeredness, we need to ensure equal access to care, i.e., decentralized diagnosis and treatment and shared and informed decision-making. We believe that digital tools have the potential to facilitate decentralized healthcare and improve patient empowerment [5].

Today, patients, relatives, and HPs do not have easy access to up-to-date information on active CTs in Denmark. This limits the patients, relatives, and the HP’s possibilities to identify and match CTs available to the patient.

The National Trial Overview (NTO) is a context-adapted digital platform with day-to-day updated overview of all CTs performed in Denmark, their status, and loca-

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tion. The NTO allows health information exchange through registries making CT information accessible to all citizens and HPs in Denmark. As such, the NTO platform is a patient-centered initiative with the potential to facilitate diversity, equity and inclusion in digital health and meet the needs of vulnerable and remote patients [6].

In this protocol paper, we present the initiative made by Trial Nation, the five regions in Denmark, and six life science companies to support the proper implementation and anchoring of NTO in the Danish healthcare system. This initiative is part of a larger project called PACT; Decentralized **Pa**tient-centered **C**linical **T**rials. Trial Nation is a public-private, non-profit association created by the Ministry of Industry, Business and Financial Affairs, the Ministry of Health, the five Danish regions, and numerous life science companies to attract commercial CTs and improve the framework for CTs in Denmark [7]. This protocol paper presents the motivation for developing the NTO platform and how to implement NTO to make CTs more accessible for patients and HPs in Denmark and increase inclusion, diversity, and equity.

2. Methods

The NTO platform will be implemented in all specialties in all hospitals in Denmark and in life science companies for approximately one year. Regional supervisors with special training in NTO will ensure the training of and handover to HPs in charge of transferring CT information to NTO. These HPs are most often research nurses, and they are included based on their role in transferring CTs to NTO.

End-user involvement is and has been crucial in designing, implementing, and evaluating the NTO platform. User involvement is facilitated through an agile user-centered design, where the users' needs and preferences are considered at the time of adaptation to the NTO platform [8]. This means an early and continuous focus on observing and understanding users' perspectives and tasks, facilitating an iterative process with possibilities for re-design or modification of the NTO platform [8,9]. In a pilot phase, the NTO platform will be implemented in two medical specialties, the respiratory medicine, and dermatological departments, in all five regions in Denmark. Here, the first author will follow and observe a regional supervisor in their handover and dialog with the HP in the respiratory medicine and dermatological departments in the five regions. The selection of the piloting departments is based on solid collaboration with the departments and their preparedness to implement the NTO system. For example, the dermatological department already has experience with using an application to match CTs to patients. Following the pilot, a workshop will be hosted for the regional supervisors and HPs in charge of transferring CT information to NTO, to evaluate the communicative, technical, and operative challenges and benefits with implementing NTO. At these workshops, the users can provide inputs to modify NTO. A follow-up evaluation in three additional specialties applying the same user-centered approach: observation of the handover between regional supervisors and HPs and workshops will guide the stepwise implementation in all specialties in Denmark.

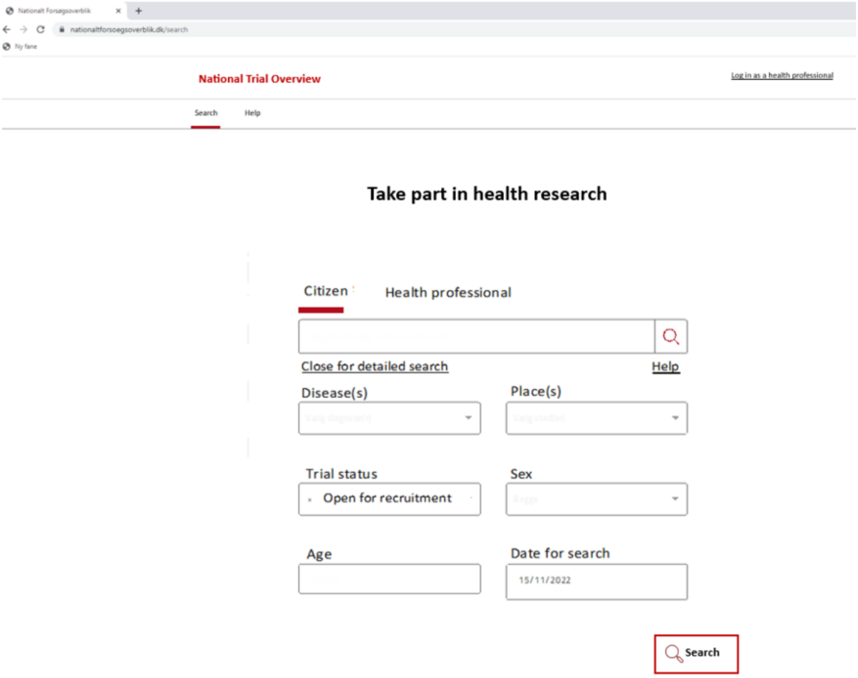
The second phase of the user-centered approach is to evaluate the citizen or patients' perspectives on NTO. This will be done by hosting focus-group discussions with patients who have used the NTO platform on their own. Users will represent both users who fall into categories of 'People like us' and 'DDDs' (Disempowered, Disengaged, and Disconnected) [10] to ensure a diverse, fair, and equal representation of users. In addition, individual user sessions will be hosted, inspired by the Interview to the Double technique [11], where users show a facilitator how they use NTO. Meanwhile the facilitator engages in a dialog with the user about NTO, based on the challenges and benefits they encounter, using the IT system. The patient's user experience will be carried out early in the implementation process, but not until numerous CTs are presented in NTO to be able to conduct a more realistic evaluation of the IT system.

We hypothesize that the user-centered design will increase NTOs functionalities, service quality, and user acceptance of the NTO platform [9].

3. Results

The motivation behind the NTO platform is to strengthen diversity, equity, and inclusion in digital healthcare. Netcompany [12] delivers the NTO platform in a collaboration between the Danish Ministry of Health, the Danish Medicines Agency, the Danish Health Data Authority, the Scientific Ethics Medical Committee, the Ministry of Industry, Business and Financial Affairs, Trial Nation, Danish Comprehensive Cancer Care, and Danish Regions with Region Zealand as project leader.

Information about CTs is accessible on the NTO platform for health information exchange between HPs and citizens or patients, but there is no sensitive, personally identifiable data in the NTO platform.



Trial status: Open for recruitment

Date for search: 15/11/2022

Figure 1. The NTO homepage (translated version).

Figure 1 illustrates a translated version of the homepage of NTO, where we meet a headline reading: "Take part in health research". It is possible to log in as a citizen and a HP. In Figure 1, the bar for advanced search for citizens has been opened (on the left side of the search bar). The citizens can search for information on disease(s); place(s);

trial status, e.g., open for recruitment or not; sex; age; and the date of searching. There is also a guide for how to search to the right. HPs can, additionally, seek information about the trial phase, type of intervention, specialty, and sponsor status. There is also a Help option, with a guide to use NTO and how to contact the NTO help disk.

The HP in charge of the CTs enters the required data into the database in the pilot phase of implementing the platform.

4. Discussion

The NTO is a novel national CT platform. An attempt to develop a platform to match patients to CTs was done in 2005 where researchers could announce their CTs and patients could view them, called trialsubject.dk [13], but the solution is no longer active. There is no formal evaluation of trialsubject.dk, which complicates the potential to learn from the implementation process. For this reason, the user-centered design to evaluate the NTO platform is essential. Primarily to adjust the NTO platform continuously, but also to create visibility about the implementation. For this reason, the NTO platform has the potential to be implemented successfully, and because of the solid public-private collaboration in both the development and implementation of the platform. Trialsubject.dk was founded by one physician and merely contained the CTs which the physicians placed in the system [13], whereas NTO will be implemented in all specialties and thereby contain an overview of all CTs in Denmark.

While a co-operative design [9] may have been considered to evaluate the NTO platform, collaboration with users is complex when designing large-scale systems with many and diverse users [9]. Therefore, a user-centered design was chosen.

The initiative of establishing an overview of CTs is not a novel phenomenon internationally. The National Library of Medicine hosts an extensive collection of CT worldwide, which transfers data automatically into a database accessible to countries, including Denmark [14]. The issue with the clinicaltrials.gov platform is that the CT information is not necessarily up-to-date, and the tool is not familiar and, thereby, not accessible to all HPs, patients, and citizens in Denmark. HPs in Denmark have therefore requested a national CT overview. The NTO will be available on the national health portal for patients and HPs, Sundhed.dk (Health.dk), which is highly and widely used in Denmark. This means that the NTO will be accessible to the Danish population and HPs, as part of building healthcare that is accessible to all regardless of logistics and connection to a health facility, and where HPs, citizens or patients can collaborate digitally about their health. Thereby, the NTO has the potential to obtain the principles of diversity, inclusion and equity in digital health [6]. Challenges to including users may be related to interoperability if the IT system cannot collaborate or due to low IT literacy among patients or poor internet access [15].

The development and implementation of the NTO is an important national initiative which can inspire and be transferred to other digitalized countries that seek a nationality-adjusted and accessible overview of CTs. Numerous countries have made attempts to make knowledge about CTs accessible to patients. For example, a commercial initiative was developed in Sydney in 2018, HealthMatch, which successfully match patients to CTs. HealthMatch is currently used in the US and Australia [16], and this solution may inspire the implementation and modification of the NTO platform.

5. Conclusions

This protocol paper presents the initiative to build and implement the NTO to make CTs more accessible to patients and HPs in Denmark and how a user-centered design is essential to implement and evaluate the NTO initiative. The paper concludes that the NTO platform has the potential to enhancing diversity, inclusion, and equity of patients and HPs, and make access to CTs more patient-centered.

In addition to implementing NTO, the PACT project will identify and map concrete and operational potentials and barriers for decentralized clinical trials (DCT) in Denmark. DCTs are patient-centered and make CTs more accessible to patients and transfer the responsibility to the patient in their home or proximity, which can be empowering [3,5].

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