How to increase patient recruitment and retention in clinical trials in Denmark?

Background

Randomized controlled trials (RCTs) are widely accepted as the gold standard for evaluating the efficacy and safety of healthcare interventions. Successful recruitment and retention of patients in clinical trials are known to be one of the most challenging aspects in the completion of RCTs.[1]

A recent analysis found that 19% of trials that were terminated in 2011 either failed to meet patient recruitment goals or were terminated early due to insufficient patient recruitment. More than 48,000 patients were involved in these trials that due to the termination were unable to answer their primary research questions. [2] Another report from 2013 found that 37% of all sites in a given trial failed to meet their enrolment targets, and more than 10% never enrolled a single patient. [3] Additionally, it has been reported that less than 5% of eligible adult cancer patients participate in clinical trials, with the main reasons for patients refusing to participate being the fear of additional burden and adverse events, and misunderstanding of trial information. [4] Lack of access and knowledge of clinical trials for some patient groups can also be a rate-limiting step in recruitment, which can slow down the study, but also lead to selection bias and unequal access to healthcare for patients.

Insufficient recruitment for trials has been estimated to double the original study timelines for phase 2 through to phase 4 in order to meet the desired enrolment targets – meaning that drugs take longer to get to the market. [3] There can also be ethical implications when trial participants are exposed to the risks associated with the trial, yet the trial is not completed and does therefore not result in any gains in scientific knowledge. [5] So, in order to bring medical innovation faster to the patients, **how can eligible patients be identified more easily regardless of physical location, education level, socioeconomic status or where they are in the healthcare system and how can the enrolment of patients be made simpler both for the study but also for the individual patient?**

Patient retention (patients enrolled in clinical trials that do not “drop out”) is another challenging aspect of conducting clinical trials. According to a recent analysis, the average dropout rate across all clinical trails is an alarming 30% (see Figure 1). The analysis suggests that, on average, across all protocol phases and therapeutic areas one needs to identify about 10 patients in order to randomize one, and only 7 of 100 known patients with the disease complete the trial.

It is a patient’s right to drop out from a trial—at any time and for any reason (which is thoroughly explained in the informed consent process),but seeing that “inconvenience” is cited as an important reason for patient drop out from clinical trials, one can wonder whether something can be done to prevent patient drop out. If the study site is far from a patient’s home or workplace, if there are multiple visits involved and if the scheduling of appointments does not fit within their routine, patients may understandably want to drop out. **So, how can clinical trials be designed to fit the patients’ lives better?**

Challenge

The current challenge is therefore to rethink RCTs to identify a higher pool of recruitable patients, make study enrolment easier, and increase retention rates in clinical trials in Denmark.
You could consider one or more of the following questions:

1) Can we utilize health registers and artificial intelligence to find the right patients for the right trial, at the right time? If so, how?
2) Can we apply digital solutions e.g. social media to increase patient recruitment? If so, how?

3) Can we utilize new digital solutions to reduce the burden of clinical trials for patients and health care professionals and thus increase patient recruitment & retention? (e.g. create virtual visits and/or extract data directly from existing health systems) If so, how?
4) Can we utilize digital solutions to predict sites that will meet their enrollment target for a given trial? If so, how?

What values and effect goals can be imagined by solving the challenge

- By utilizing digital solutions to find patients, a broader sample of the population could be screened for recruitment.
- By making patient recruitment into clinical trials more modernised/digitalised, one could foresee a greater proportion of patients with a given disease being presented with the possibility of participating
- A higher proportion of completed trials and faster completion of trials could lead to innovative medicines reaching patients faster.

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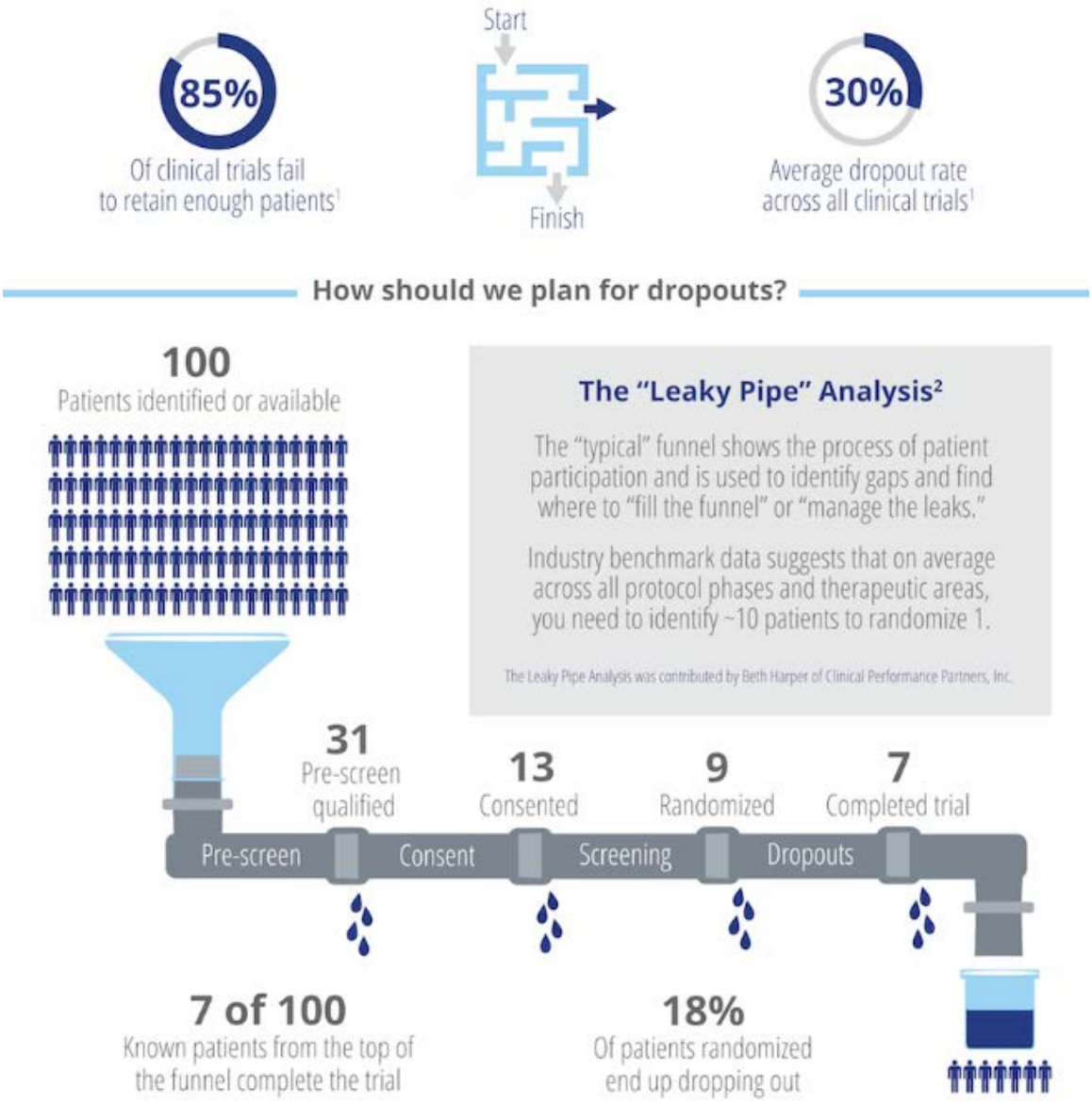

Figure 1:The "Leaky Pipe" Analysis