# Strategies to **optimize site & investigator experience**

in clinical trial design utilizing digital measurement of nocturnal scratch

## NOCTURNAL SCRATCH

*Digital Measures Development*

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A project by the DIGITAL MEDICINE SOCIETY

# Three main aspects

have been identified, enabling sponsors to form strategies to optimize site and investigator experience in clinical trials design utilizing digital technologies, such as digital measurement of nocturnal scratch

Building positive relationship & motivation

Minimizing site overhead

Providing adequate training & support

# Building positive relationships & motivation

Sponsors shall **consult with sites early on** - early pre-selection & building relationships prior to protocol design is beneficial to address details, concerns, and challenges of the collaboration. Some questions to consider include:

- ? Are relevant site perspectives being sought from the earliest stages of trial planning?
- ? Have patients and sites been involved in technology selection?
- ? Have protocol elements been weighed against the potential added burden on participants and sites?

**Using digital technologies in research is often a novelty for sites.** Sponsors should help sites understand the concepts, tasks, & KPIs associated with trials using digital health technologies

Sponsors shall be **clear & upfront** around tasks & KPIs required from the site, with **appropriate compensation** for these tasks and activities

- It may be strategic to set up the budget with flexibility to account for unknowns
- Think about whether the digital assessments you want to add shall be mandatory or optional. Marking them as 'mandatory' might result in better engagement from both sites and patients

Sponsors shall think about creating **multi-faceted methods of communication throughout the processes** before and during the clinical trial - *such as memos, CRAs, auditors, emails, phone, chatbots, virtual assistants, etc.*

- In these communications, design proactive check-ins from sponsor towards site, such as reminders, newsletters, or other forms of communication

# Minimizing site overhead

**Look for ways to decrease number of in-person patient visits**

- Keep visits to minimally required safety samples or injections necessary. Using DHTs should not create the need for additional visits

**Avoid the need for duplicate data entries** *(e.g. to different IT systems, or paper+electronic, etc.)*

**Be clear about requirements** for the site to remotely monitor incoming data or technology performance throughout the study conduct

- Cloud-based platforms are more manageable than manual remote monitoring - the more automated this process can be, the less burden it will have on the site

**Selected digital technologies should be easy to set-up** - ideally coming pre-set directly from the technology vendors

**Design simple, easy, & engaging onboarding for the first use of digital technologies**

- **For the site personnel:** For example, an onboarding flow accompanied by additional materials upon turning on and set up of the device or technology by site personnel
- **For the patients:** Patients will often have the first contact with the technology at the site

**Consider adding trial-use (testing) of the technology** *(e.g. as a protocol simulation)* to the trial design to uncover unanticipated issues with technology performance or use

- Issues may include performing, trying out, and troubleshooting the day-to-day actions *(charging, cleaning, data transfer, etc.)* should be simple

**Pro tip!** You don't want to train clinical teams until the digital technology products have been configured (e.g., don't draft patient guides and site manuals until the product is agreed on). These materials should be clear around who is handling additional tech support when issues arise.

# Providing adequate training & support

**Define** what the relationship between the technology vendor and the site will look like prior to and during the trial

- Will the vendor directly provide support to sites (e.g., the devices, cloud-based portals, etc.)?
- If not, will there be a middleman in this support and communication?

**Site training materials should address all concerns patients may have,** including about DHTs (privacy concerns, ease of use, skin irritation, etc.)

Site training materials should be appropriate for age groups the sites will be interacting with

- In the case of atopic dermatitis, age groups may include younger children or caregivers for infants

Provide training materials in **various formats** (e.g. paper, mobile app, website, etc.) and make training materials visual & interactive

- For example, use of graphics, screenshots, video content, virtual assistant, e-learning, chatbots, etc.
- Enable site personnel and patients to test & try out devices hands-on prior to the trial as a part of training

**Create repository of important information**, such as an online portal with Q&As, and keep it updated regularly

**Provide clarity** to site personnel as well as patients about he "who, where, & how" of how tech support is provided to them and to the patients in the trial

## Additional Relevant Resources

- CTTI - Optimizing Mobile Clinical Trials by Engaging Patients and Sites
- CTTI - Considerations in Selecting and Equipping Sites for Clinical Trials with Mobile Technologies
- CTTI: Selecting Mobile Technologies for Data Capture in Clinical Trials *(Page 20: Protocol Design and Execution)*
- The Playbook: Worksheet: Preparing and Assisting Sites and Participants for Success with the Digital Sensing Product
- The Playbook: Clinical trial operations - distribution
- The Playbook: Will this cause confusion/frustration at the clinical sites?
- The Playbook: Usability and Utility section (slides 139-145)

## Additional Considerations

Defined in the selected **Additional Relevant Resources** on this page shall be applied to optimize the site experience in clinical trials deploying digital technologies.

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