Project charter template for clinical studies utilizing digital measurement of nocturnal scratch

Study Project Charter Prepared by:	
Document Date:	
Document version:	

1. Study Overview

Study Purpose and Study Phase Describe the reason(s) for initiating the Study, specifically stating the research problem. Describe the value the study results will provide.	
Study Goals and Objectives Describe the main study goals and objectives. These goals may come from the study protocol if that has been already developed, or can be high-level if the study protocol has not yet been developed.	
Study Endpoints Describe intended study endpoints (primary, secondary, exploratory). These endpoints may come from the study protocol if that has been already developed, or can be high-level if the study protocol has not yet	

been developed.	
Study Population Describe study population and inclusion/exclusion criteria in low-fidelity detail. This information may come from the study protocol if that has been already developed, or can be high-level if the study protocol has not yet been developed.	
Study Scope Describe the study scope. The scope establishes boundaries and should describe products and/or services that are both inside and outside of the scope. If developed, add information about the planned duration of the trial and its timeline, planned visits, or planned countries and regions.	
Critical Success Factors Describe the factors or characteristics that are deemed critical to the success of a project such that, in their absence, the study would fail.	
Assumptions Describe any assumptions related to the patient population, technology, resources, scope, expectations, or schedules.	
Risks Describe a high-level overview of major threats to the study success based on the study goal (measure or drug development). Think also about the risks associated with the use of the DHT in the study.	
Constraints Describe any constraints being imposed in areas such as schedule, budget, resources, products to be used, technology to be employed, products to be acquired, and interfaces to other products.	

2. Study Authorities and Milestones

Funding Authority and Budget Identify the funding authority and source of authorizations for the funding and state overall budget for the study.	
Study Oversight Authorities Describe the management of the study. Describe internal and external oversight bodies, including PI, IRBs, or project management personnel.	
Major Study Milestones List the major milestones and deliverables and the planned completion dates for delivery.	

3. Roles and Responsibilities

Summarize roles and responsibilities for the study core team and main stakeholders.

Think about roles and responsibilities in the study execution, such as:

- Vendor selection & relations
- IRB review
- Site & participant trainings and material development
- Shipping & inventory allocation
- Technical support
- Data ingestion
- Compliance monitoring
- Data analysis
- Etc.

Name/Role	Responsibility

4. Study Facilities and Resources

Describe the study requirements for facilities and resources, such as clinical visit space, special facilities, computer or mobile equipment (including the selected measurement technology hardware and, if applicable, algorithm or software for analysis), and other support tools. Identify responsibilities by role for provisioning the specific items needed to support the study.

Resource/Requirement	Responsibility

5. Glossary

Define all terms and acronyms required to interpret this project charter properly.

Term or acronym	Definition

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Additional Relevant Resources:

- The Playbook: Benefits matrix
- The Playbook: How will this endpoint benefit our trial?
- The Playbook: Operational considerations for successful technology selection and implementation
- The Playbook: Additional infrastructure needed to support deployment of a digital measure