ClinOps Ontology Project

Vision:
Have a unified, open, machine-readable metadata backbone that provides all necessary information to automatize clinical study operations

Goal (Q1 to Q3 2024):
Leveraging existing ClinOps standard to prove the concept (PoC) that a ClinOps ontology will accelerate the process of site selection and site support with running clinical procedures as defined in a study protocol schedule of assessment data

Project Lead: Aditya Tyagi
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Project Steering Team

Provide direction and make strategic decisions on project priority tasks

Sponsoring organizations

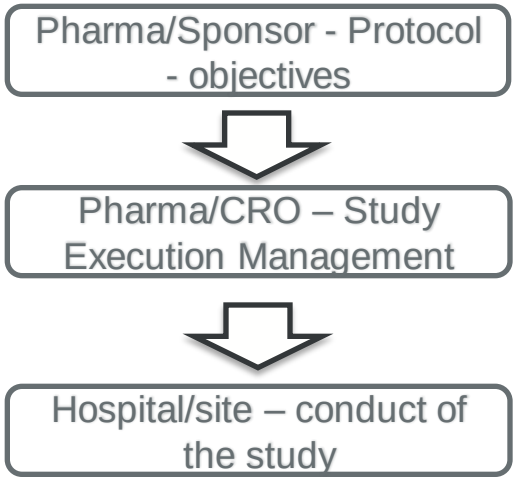
NOVARTIS Roche MERCK Boehringer Ingelheim ...

Project Champions	**Merck KGaA:** Gernot Weber, Hrvoje Mohoric, Stefan Gilb
	Roche: Marcel Merfort, Cedric Berger
	Novartis: Artur Schaf, Rudi Ager
	Boehringer Ingelheim: Karsten Quast

First Use Case – Site Feasibility

Protocol and Schedule of Activities

- Site feasibility - align requirements of protocol with capabilities of a site
- What is protocol and schedule of activities/events?
- Pharma, CRO, site relationship
- Manual process

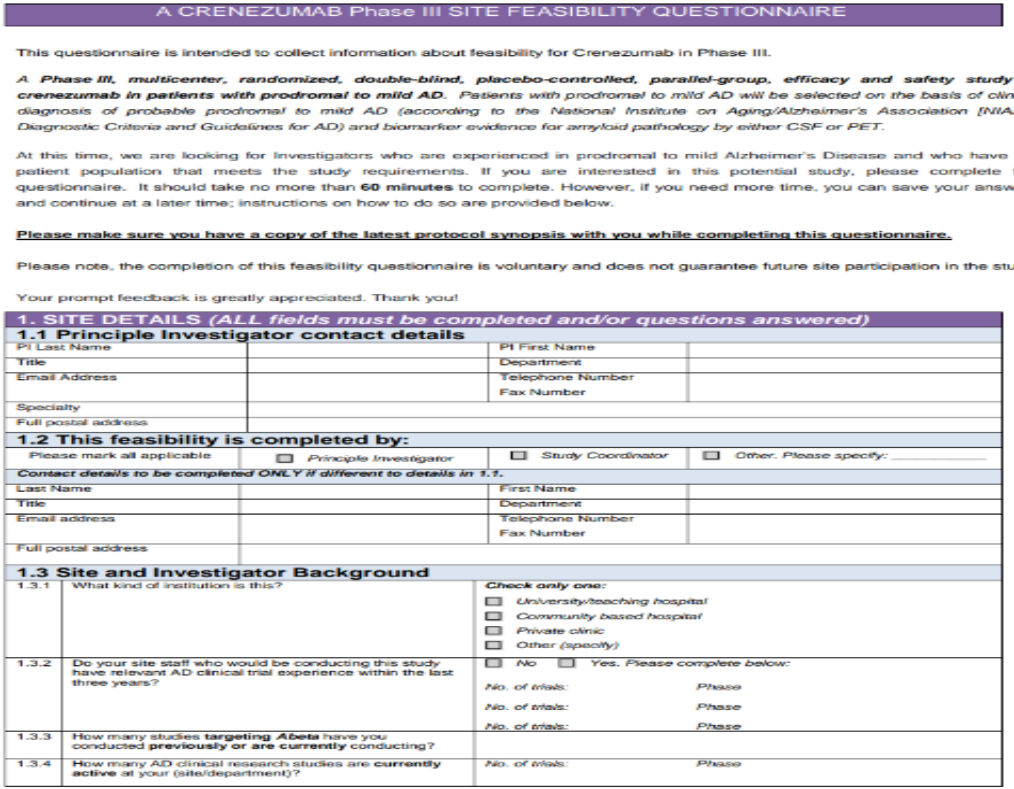


Schedule of Activities: Open-Label Extension Study

Assessment/ Procedure		Open-Label Extension							Follow-Up for Pts Discontinuing OLE Treatment			Follow-Up for Pts Completing OLE Treatment [a]	
	OLE Scrn. [b]	Visit 1 OLE Wk 1 [c]	OLE Wk 5 and Every 4 Wks thereafter (±7 days) [c]	Visit 4 OLE Wk 13 (±7 days) [c,d]	OLE Wk 25 (±7 days) [c,d]	OLE Wk 53 (±7 days) [c,d]	OLE Wk 77 (±7 days) [c,d]	OLE Wk 105 and Every 52 Wks thereafter (±7 days) [c,d]	Last Dose in OLE +4 Wks (or ET)	Last Dose in OLE +16 Wks	Final Annual Visit for OLE Discon. before Wk 53/105 [e]	Last Dose in OLE +4 Wks	Last Dose in OLE +16 Wks
Informed consent for OLE	x												
Review of OLE eligibility criteria	x												
Coagulation blood test	x [f]												
Vital signs [g]		x	x	x	x	x	x	x	x	x	x	x	x
Urinalysis [h]					x	x	x	x	x	x		x	x
Urine pregnancy test [i]		x	x	x	x	x	x	x	x			x	
PK serum sample [j]		x		x [k]	x [k]	x		x	x	x		x	x
Immunogenicity sample [l]		x		x	x	x		x	x	x		x	x
Amyloid-PET/tau-PET/CSF [m,n]						x [n]			x [n]				
PD plasma sample [j,o]						x [n]			x [n]				
12-Lead ECG [g]					x	x		x	x			x	

Site Feasibility Questionnaire

- What is site feasibility questionnaire - collect information from sites manually
- Multiple stake holders manually summarize to design questionnaire
- Feasibility team prepares the summary and finalize site selection
- For other study, process repeats asking sites the same questions again and sites must fill the similar information again



A CRENEZUMAB Phase III SITE FEASIBILITY QUESTIONNAIRE

This questionnaire is intended to collect information about feasibility for Crenezumab in Phase III.

*A **Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group, efficacy and safety study of crenezumab in patients with prodromal to mild AD**. Patients with prodromal to mild AD will be selected on the basis of clinical diagnosis of probable prodromal to mild AD (according to the National Institute on Aging/Alzheimer's Association [NIAAA] Diagnostic Criteria and Guidelines for AD) and biomarker evidence for amyloid pathology by either CSF or PET.*

At this time, we are looking for Investigators who are experienced in prodromal to mild Alzheimer's Disease and who have the patient population that meets the study requirements. If you are interested in this potential study, please complete this questionnaire. It should take no more than **60 minutes** to complete. However, if you need more time, you can save your answers and continue at a later time; instructions on how to do so are provided below.

Please make sure you have a copy of the latest protocol synopsis with you while completing this questionnaire.

Please note, the completion of this feasibility questionnaire is voluntary and does not guarantee future site participation in the study.

Your prompt feedback is greatly appreciated. Thank you!

1. SITE DETAILS *(ALL fields must be completed and/or questions answered)*

1.1 Principle Investigator contact details

PI Last Name		PI First Name	
Title		Department	
Email Address		Telephone Number Fax Number	
Specialty			
Full postal address			

1.2 This feasibility is completed by:

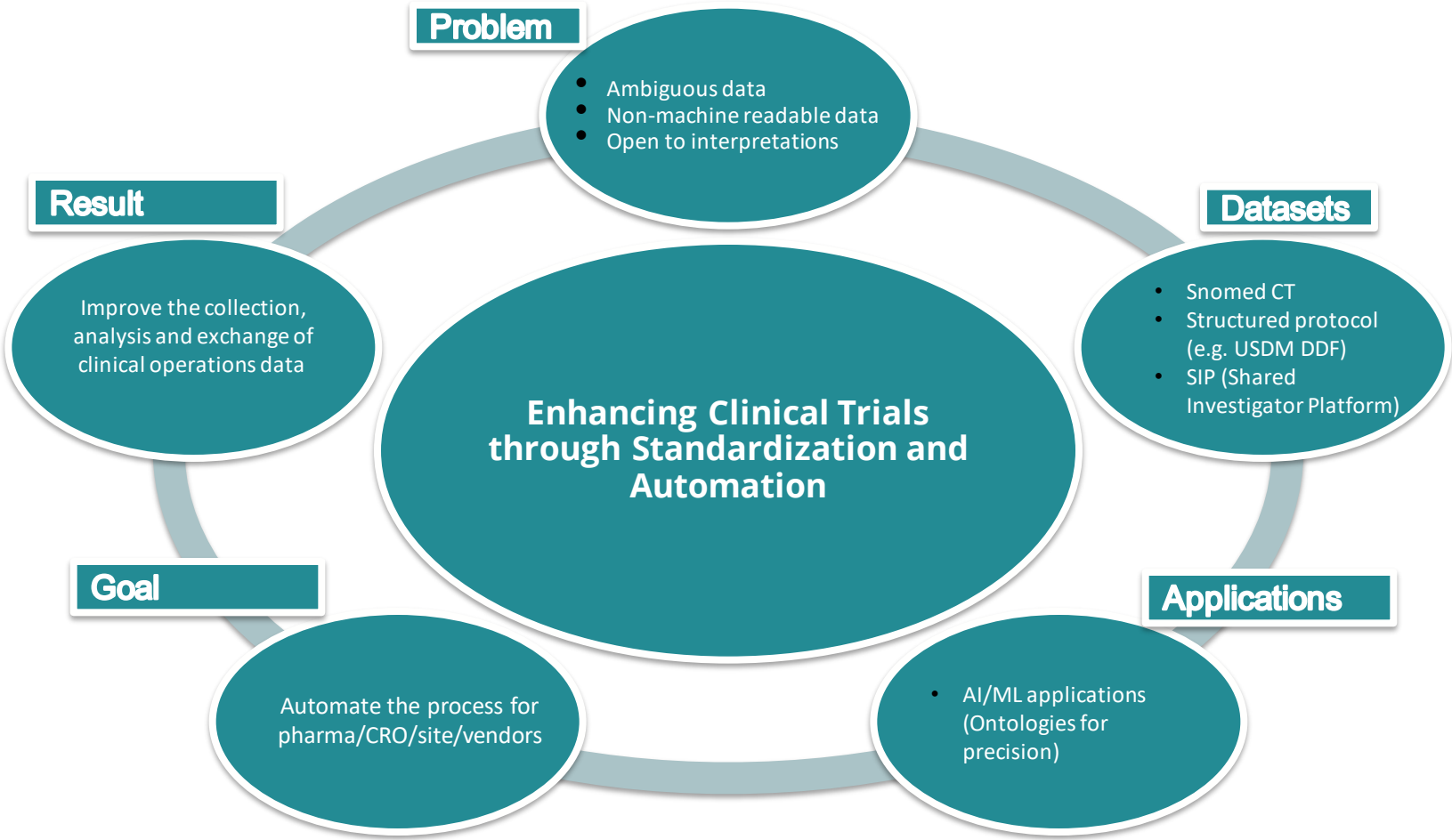
Please mark all applicable	☐ *Principle Investigator*	☐ *Study Coordinator*	☐ *Other. Please specify:* _____

Contact details to be completed ONLY if different to details in 1.1.

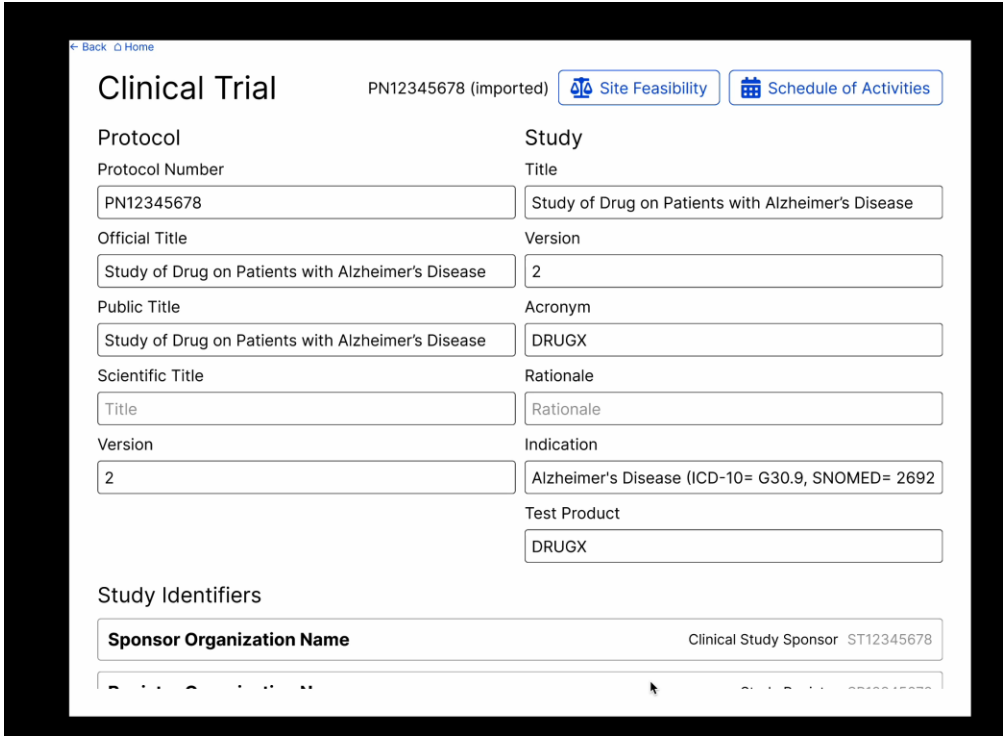
Last Name		First Name	
Title		Department	
Email address		Telephone Number Fax Number	
Full postal address			

1.3 Site and Investigator Background

1.3.1	What kind of institution is this?	***Check only one:*** ☐ *University/teaching hospital* ☐ *Community based hospital* ☐ *Private clinic* ☐ *Other (specify)*
1.3.2	Do your site staff who would be conducting this study have relevant AD clinical trial experience within the last three years?	☐ *No* ☐ *Yes. Please complete below:* *No. of trials:* *Phase* *No. of trials:* *Phase* *No. of trials:* *Phase*
1.3.3	How many studies **targeting *Abeta*** have you conducted **previously or are currently** conducting?	
1.3.4	How many AD clinical research studies are **currently active** at your (site/department)?	*No. of trials:* *Phase*



Clinical Operation Ontology Demo



Join us and get involved

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