ICH GCP R3

Hva betyr det for oss?

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ICH harmonisation for better health

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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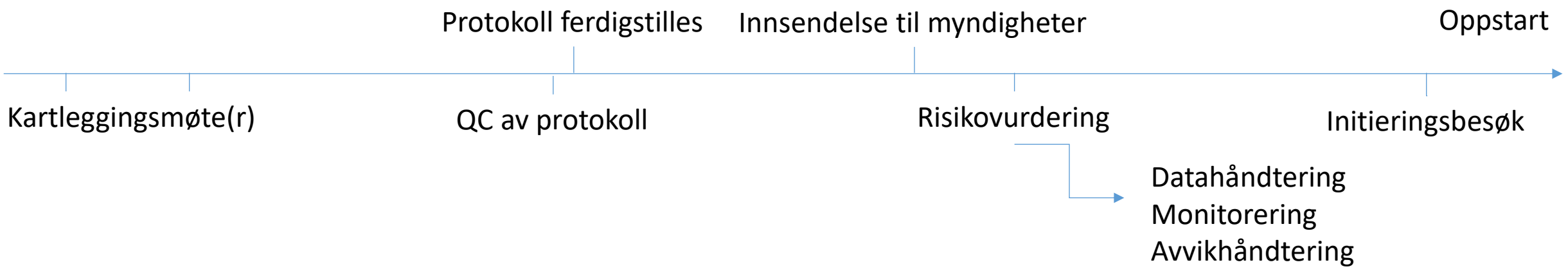
EMA/CHMP/ICH/135/1995
Committee for Human Medicinal Products

ICH E6 (R3) Guideline for good clinical practice (GCP)

Step 5

Transmission to CHMP	25 May 2023
Adoption by CHMP	25 May 2023
Release for public consultation	26 May 2023
Deadline for comments	26 September 2023
Final adoption by CHMP	12 December 2024
Date for coming into effect	23 July 2025

Forskerens vei med CTU i planleggingsfasen



Rådgivningsmøter ved behov

Fit for purpose, quality by design

Objective	Endpoints	Assessment
Primary		
To compare early neurological improvement (ENI) between patients treated with IVT within 4.5 hours after stroke onset and patients treated with the current standard of care.	ENI, defined as a reduction of ≥8 points on the National Institutes of Health Stroke Scale (NI NIHSS of 0-1 at 24 hou	NIHSS
Secondary efficacy		
To compare clinical neurological improvement between patients treated with IVT and patients treated with the current standard of care.	Percentage change in N baseline to 24 h (22-36	
To compare infarct volume at CT/MRI at 24h ±12 hours between patients treated with IVT and patients treated with the current standard of care.	Percent change in infarc 24 h ± 12 hours.	

Procedure	Intervention Period				Follow-up	Notes
	0 hours baseline	+ 2 h	+ 24 h (22-36 h)	+ 7 days or earlier discharge	90 days +/- 2 weeks	
Demography*	X					Age, sex, ethnicity
Current and prior medical conditions*	X					Described in 1.3.1
Vital signs*	X	X	X			Described in 1.3.1
NIHSS score*	X	X	X**	X		Described in 1.3.1 and section 3
Imaging* Head CT/CTA(CTP) or MRI (MRA/MRP)	X		X (24 h +/- 12h)			Described in 1.3.1
Inclusion and exclusion criteria	X					Described in 5.1-5.2
Laboratory analysis*	X		X			Appendix 2
Biobank	X***(****)		X****			Described in 9.8.1
Informed consent	X					Described in 11.1.3
Randomization	X					Described in 4.1
Study intervention (alteplase/tenecteplase))	X					
12-lead ECG*		X				
SAE/AE*	X	X	X	X		Described in 1.3.2/9.3/11.1.6
Telephone; mRS, EQ5D-5L,T-MoCA*****					X	Described in 1.3.5/3.1

*SOP for any thrombolysis, ** the NIHSS scoring at 24 h will be done by blinded study personnel, ***one extra citrated tubes for bio banking in the ED. ****If possible, contribute to more extensive bio banking day 0 and 1, ***** by dedicated study nurse OUS

Er det noe vi kan justere?

- Kan vi unnlate arkivering av enkelte dokumenter?
  - Arbeidssedler fra apotekene?
- Registrering i eCRF:
  - Lab: sikkerhetsmålinger?
  - Tilleggsmedisinering?
  - Pasientrapporterte utfallsmål?
  - Uønskede hendelser?

Egen ICH-retningslinje for sikkerhetsrapportering i senere utviklingsfaser E19 – Implementert i EØS 16. mars 2023

2.4 Data that Should Generally be Collected

1. Serious adverse events (see ICH E2A; ICH E6)
2. Important medical events (see ICH E2A)
3. Medication error/overdose (intentional or unintentional)
4. Adverse event that led to study drug discontinuation
5. Pregnancy and lactation exposure and outcomes
6. Adverse events of special interest, including laboratory abnormalities, identified in the protocol as critical to safety evaluations (see ICH E6; ICH E2F: Development Safety Update Report; CIOMS VI).

2.5 Data that May be Appropriate for Selective Collection

1. Non-serious adverse events may not need to be collected, or collection may be reduced in frequency.
2. Various types of laboratory monitoring (e.g., serum chemistries, haematology) electrocardiograms, and imaging trials may not be necessary, or monitoring may be performed at a reduced frequency.
3. Physical examinations and vital sign data may not need to be collected or may be collected at reduced frequency.
4. Once concomitant medication use is documented at baseline, changes in concomitant therapies (e.g., changes in dose, added therapies, discontinuation of therapies) may not need to be collected.

TABLE OF CONTENTS

Mye er på plass

- En god protokollmal (Transcelerate)
- Prosedyrer for statistikk og datahåndtering finnes, skal justeres
- Den risikobaserte tankegangen er godt innarbeidet i våre prosedyrer

- Og noe må vi jobbe mer med…

Krav til oversikt (oversight)

- Sikkerhet
- Etterlevelse av protokoll og studiespesifikke prosedyrer
- Avviksregistrering
- Rapportering
- Progresjon i studien
- Ressurser
- …

Dokumentering og kommunikasjon

Validering av datasystemer

For sponsor:

- Viktig at både datasystemene samt bruken i studien er validerte, f.eks.
  - Viedoc er en validert datafangstløsning for legemiddelstudier og
  - Studieoppsettet i Viedoc er validert (user acceptance testing)

For hovedutprøvere:

- Datakildene skal være validerte, eSource Assessment Tools

Hvor langt har vi kommet?

GCP-kursene ved HUS, St. Olavs og OUS er i henhold til ICH GCP R3

Alle prosedyrene for legemiddelutprøvinger (SOP-er med sjekklister og maler) skal oppdateres innen 23. juli 2025