COMPETENCE CENTRE
FOR METHODOLOGY
AND STATISTICS

LUXEMBOURG
INSTITUTE
OF HEALTH

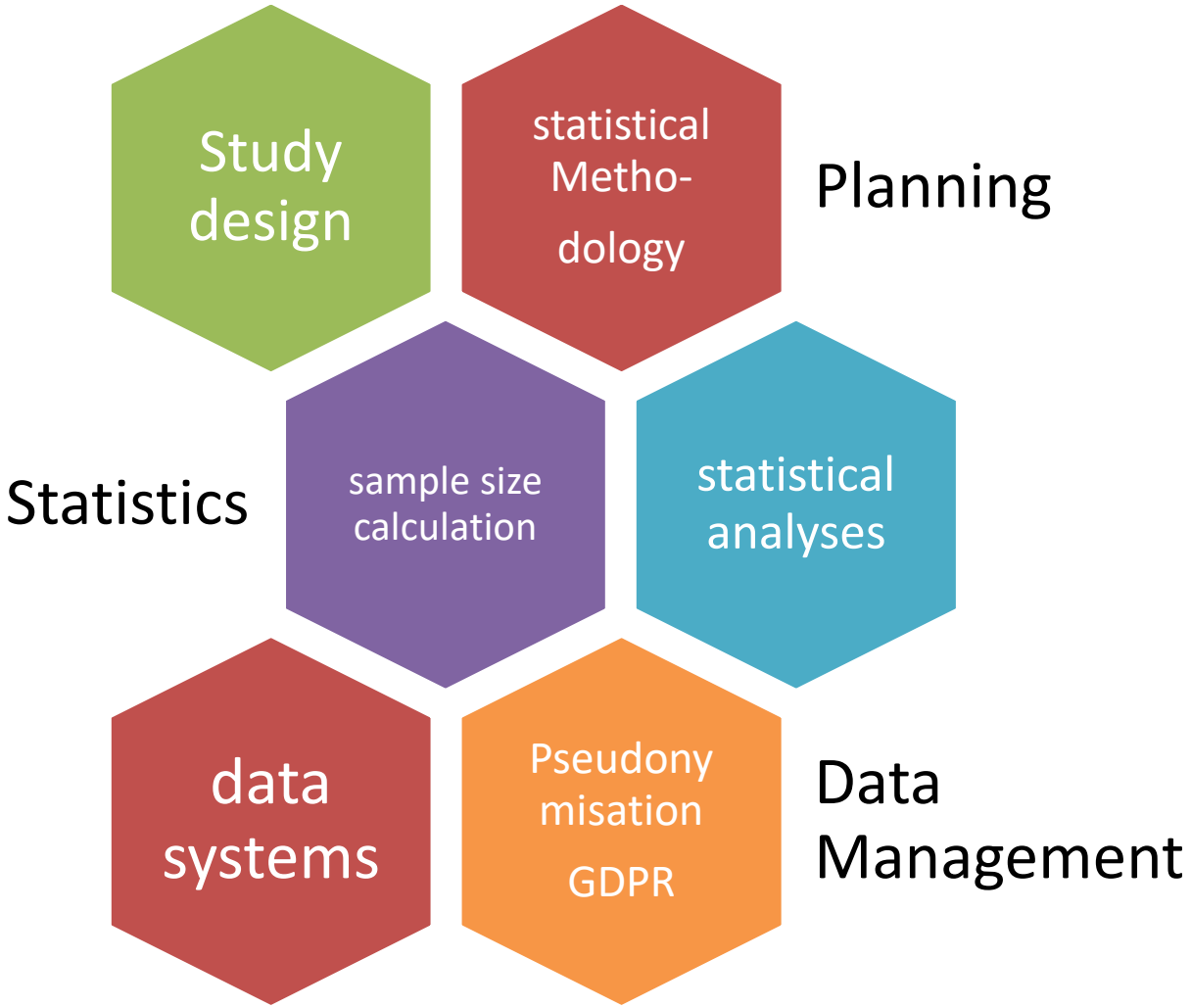
TRANSLATIONAL
MEDICINE
OPERATIONS HUB
TMOH

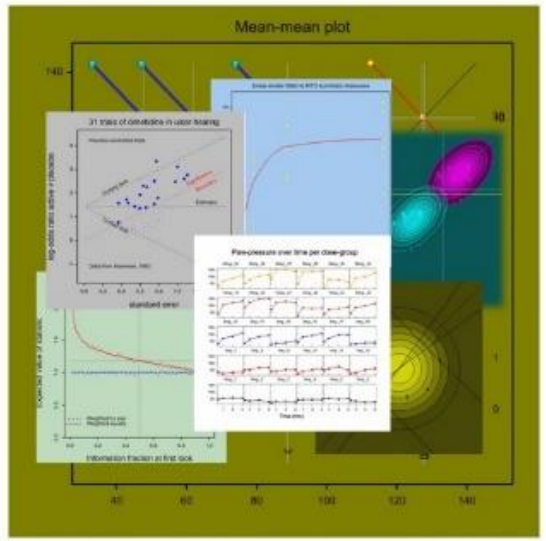
Competence Centre for Methodology and Statistics

Michel Vaillant, Mstat, Mepid, PhD

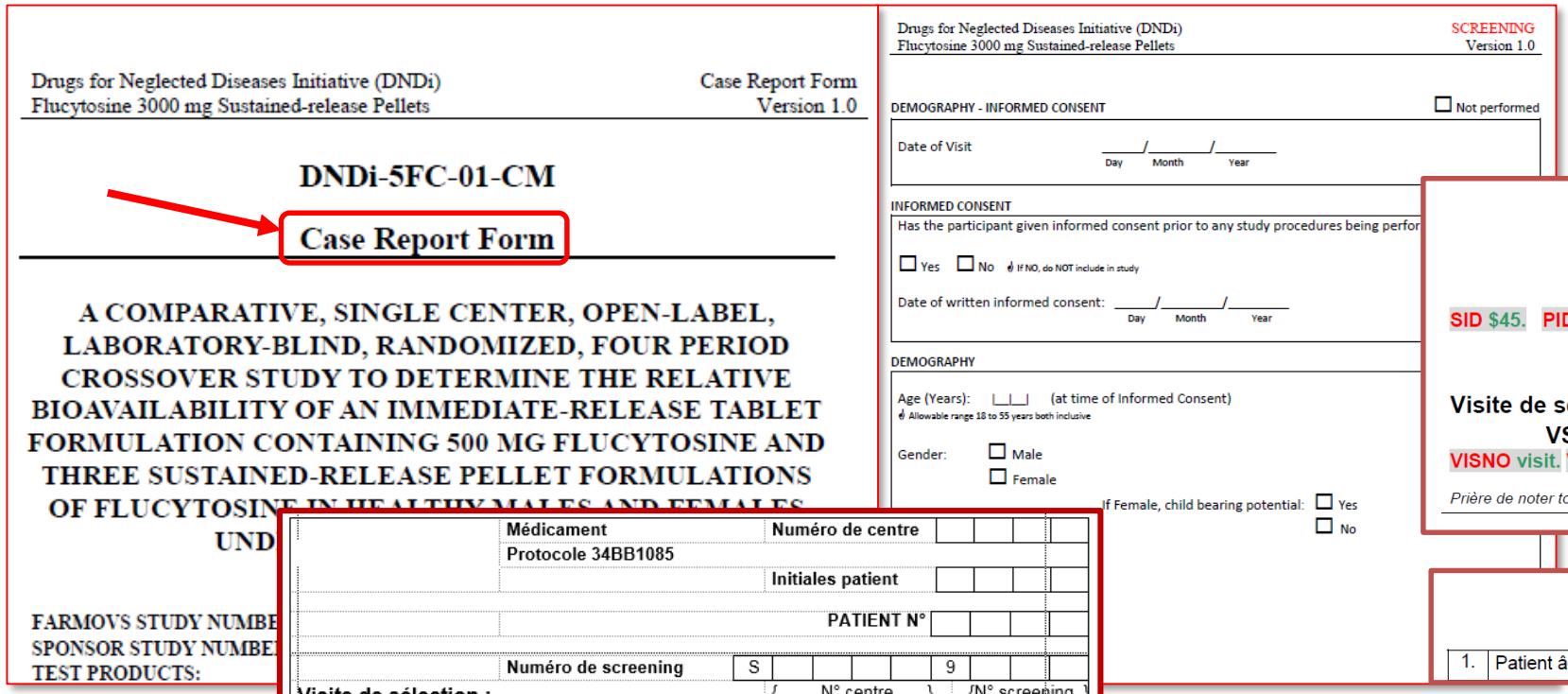
Head of Unit

CCMS missions





Clinical Data Management: CRF Design and annotation



Drugs for Neglected Diseases Initiative (DNDi)
Flucytosine 3000 mg Sustained-release Pellets

Case Report Form
Version 1.0

DNDi-5FC-01-CM

Case Report Form

A COMPARATIVE, SINGLE CENTER, OPEN-LABEL, LABORATORY-BLIND, RANDOMIZED, FOUR PERIOD CROSSOVER STUDY TO DETERMINE THE RELATIVE BIOAVAILABILITY OF AN IMMEDIATE-RELEASE TABLET FORMULATION CONTAINING 500 MG FLUCYTOSINE AND THREE SUSTAINED-RELEASE PELLET FORMULATIONS OF FLUCYTOSINE IN HEALTHY MALES AND FEMALES UND

FARMOVS STUDY NUMBE
SPONSOR STUDY NUMBE
TEST PRODUCTS:

Drugs for Neglected Diseases Initiative (DNDi)
Flucytosine 3000 mg Sustained-release Pellets

SCREENING
Version 1.0

DEMOGRAPHY - INFORMED CONSENT ☐ Not performed

Date of Visit ____/____/____ Day Month Year

INFORMED CONSENT

Has the participant given informed consent prior to any study procedures being perfor

☐ Yes ☐ No ⇩ If NO, do NOT include in study

Date of written informed consent: ____/____/____ Day Month Year

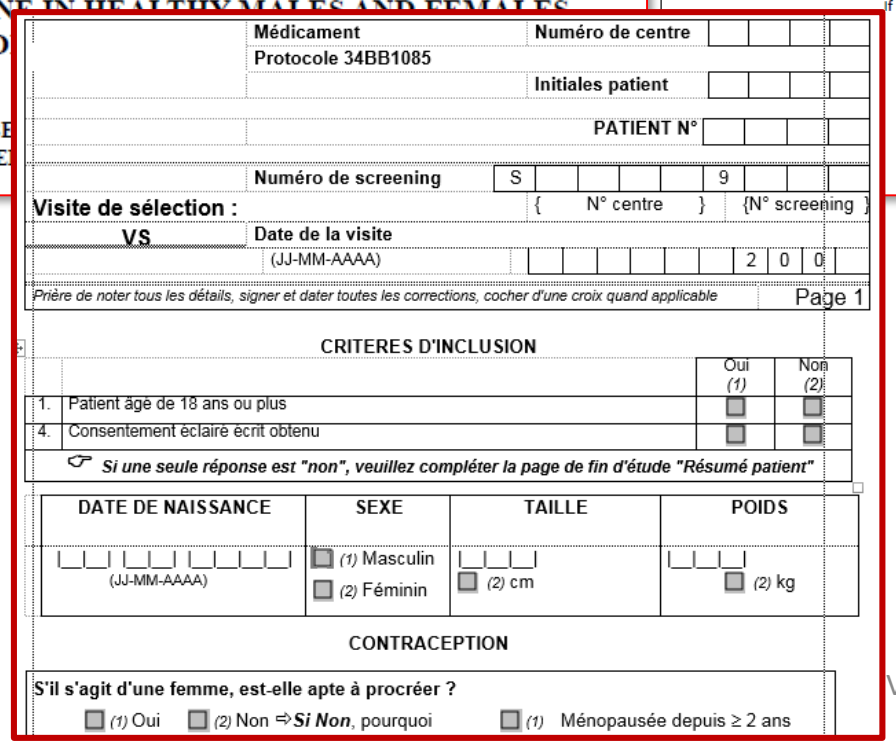
DEMOGRAPHY

Age (Years): |_|_| (at time of Informed Consent)

⇩ Allowable range 18 to 55 years both inclusive

Gender: ☐ Male ☐ Female

If Female, child bearing potential: ☐ Yes ☐ No



Médicament | Numéro de centre
Protocole 34BB1085
Initiales patient
PATIENT N°
Numéro de screening S | 9
Visite de sélection : { N° centre } {N° screening }
VS
Date de la visite (JJ-MM-AAAA) 2 0 0

Prière de noter tous les détails, signer et dater toutes les corrections, cocher d'une croix quand applicable Page 1

CRITERES D'INCLUSION

		Oui (1)	Non (2)
1.	Patient âgé de 18 ans ou plus	☐	☐
4.	Consentement éclairé écrit obtenu	☐	☐

☞ ***Si une seule réponse est "non", veuillez compléter la page de fin d'étude "Résumé patient"***

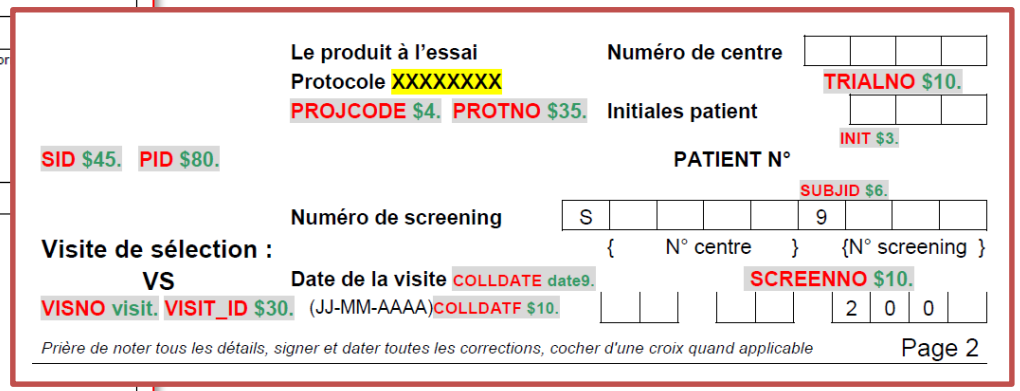
DATE DE NAISSANCE	SEXE	TAILLE	POIDS
|_|_| |_|_| |_|_|_|_| (JJ-MM-AAAA)	☐ (1) Masculin ☐ (2) Féminin	|_|_|_| ☐ (2) cm	|_|_|_| ☐ (2) kg

CONTRACEPTION

S'il s'agit d'une femme, est-elle apte à procréer ?

☐ (1) Oui ☐ (2) Non ⇨ ***Si Non***, pourquoi ☐ (1) Ménopausée depuis ≥ 2 ans

Data handling

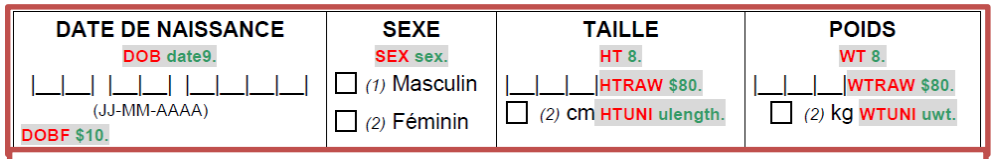


Le produit à l'essai
Protocole XXXXXXXX
PROJCODE $4. PROTNO $35.
Numéro de centre
TRIALNO $10.
Initiales patient
INIT $3.
SID $45. PID $80.
PATIENT N°
SUBJID $6.
Numéro de screening S | 9
Visite de sélection : { N° centre } {N° screening }
VS
VISNO visit. VISIT_ID $30.
Date de la visite COLLDATE date9.
SCREENNO $10.
(JJ-MM-AAAA)COLLDATF $10. 2 0 0

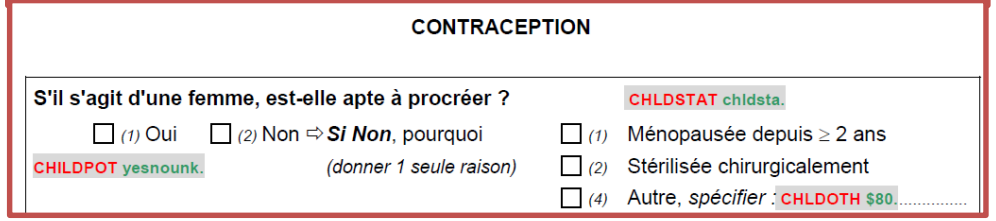
Prière de noter tous les détails, signer et dater toutes les corrections, cocher d'une croix quand applicable Page 2

CRITERES D'INCLUSION

		Oui (1)	Non (2)
1.	Patient âgé de 18 ans ou plus IC1 yesno.	☐	☐



DATE DE NAISSANCE	SEXE	TAILLE	POIDS
DOB date9. |_|_| |_|_| |_|_|_|_| (JJ-MM-AAAA) DOBF $10.	SEX sex. ☐ (1) Masculin ☐ (2) Féminin	HT 8. |_|_|_|HTRAW $80. ☐ (2) cm HTUNI ulength.	WT 8. |_|_|_|WTRAW $80. ☐ (2) kg WTUNI uwt.



CONTRACEPTION

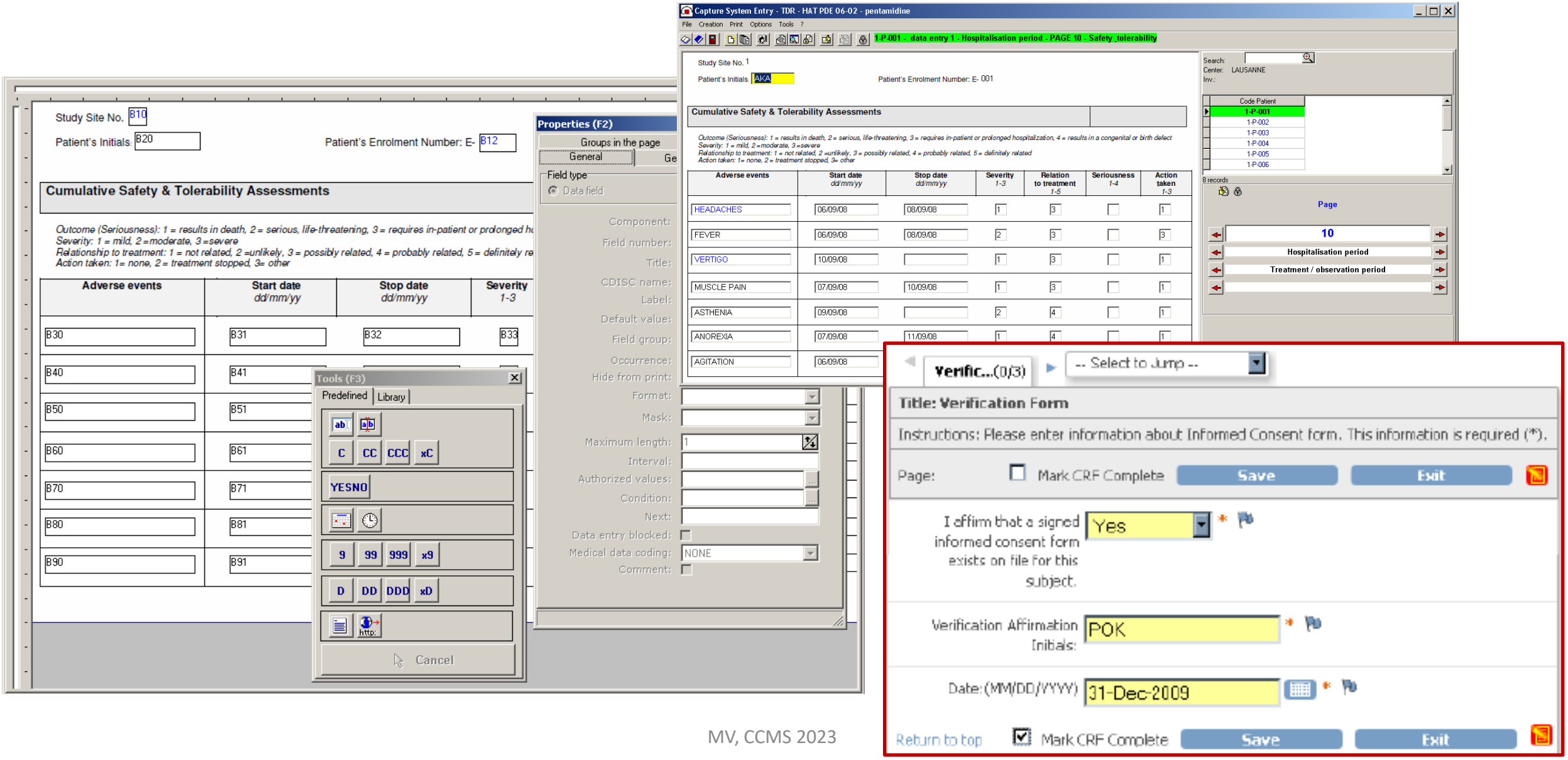
S'il s'agit d'une femme, est-elle apte à procréer ? CHLDSTAT chldsta.

☐ (1) Oui ☐ (2) Non ⇨ ***Si Non***, pourquoi CHILDPOT yesnounk.

(donner 1 seule raison)

☐ (1) Ménopausée depuis ≥ 2 ans
☐ (2) Stérilisée chirurgicalement
☐ (4) Autre, *spécifier* : CHLDOTH $80.

Clinical Data Management: Database design & Data Entry



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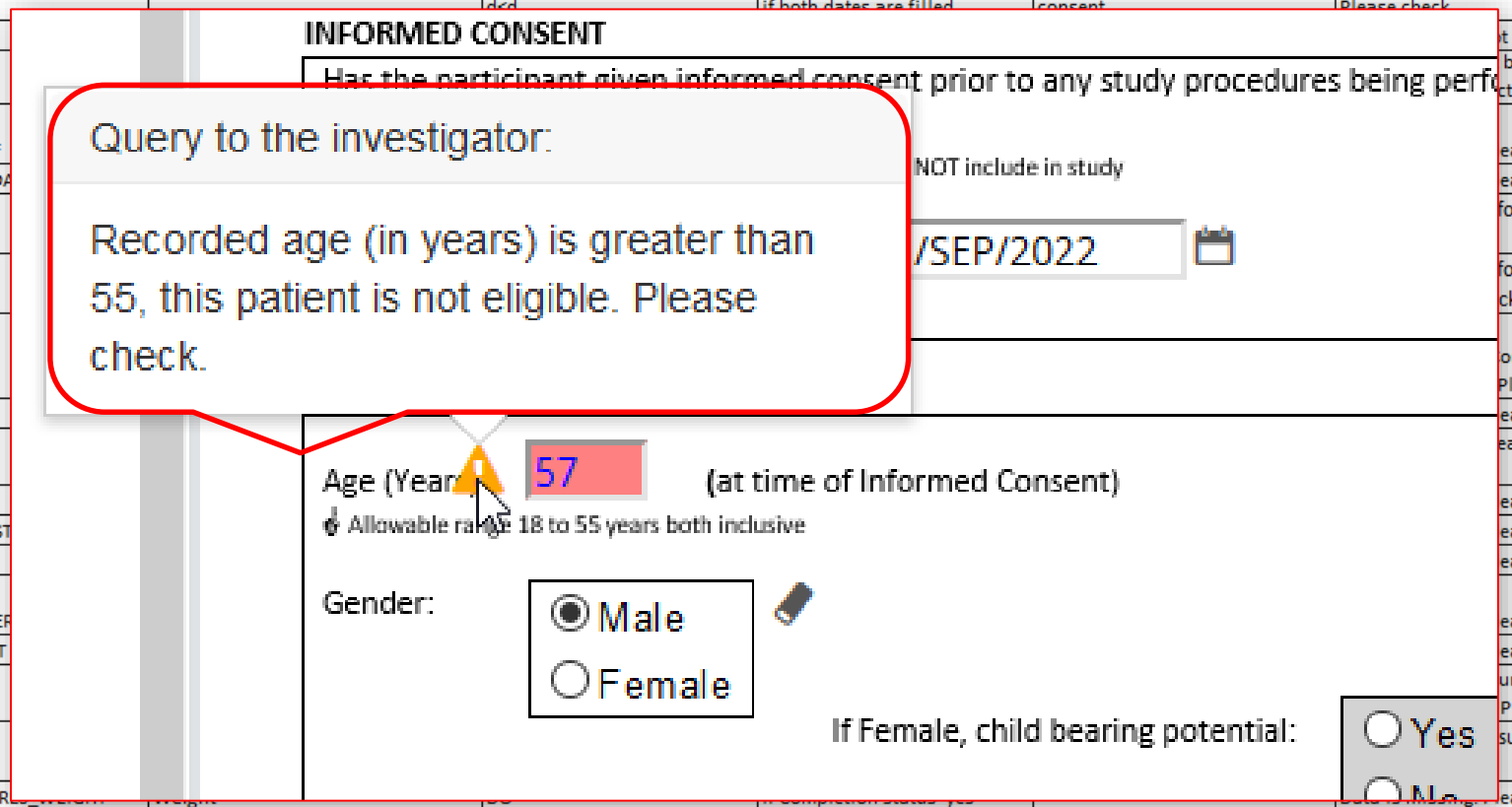
Clinical Data Management: Data Quality

Visit Name	Form Name	Variable Code	Variable Label	Test Option	Condition	Test Description	Question for investigator
Screening	Demography - Informed consent	DMPERF	Completion status Demography	DO			Data is missing. Please enter data.
Screening	Demography - Informed consent	RFSTDTC	Date of visit	DO	if Completion status=yes		Data is missing. Please enter data.
Screening	Demography - Informed consent		Date of visit	dcd	if both dates are filled	Date of visit < Date of Informed consent	Date of visit is before Date of written informed consent. Please check.
Screening	Demography - Informed consent						t be in the future, please check.
Screening	Demography - Informed consent						between -21 days before Date of first ct or clarify.
Screening	Demography - Informed consent	DSICF					ease enter data.
Screening	Demography - Informed consent	RFICDA					ease enter data.
Screening	Demography - Informed consent						formed consent cannot be before
Screening	Demography - Informed consent						formed consent cannot be in the ck.
Screening	Demography - Informed consent						onsent is not between -21 days before Please correct or clarify.
Screening	Demography - Informed consent	AGE					ease enter data.
Screening	Demography - Informed consent						ears) is less than 18 or greater than 55.
Screening	Demography - Informed consent	SEX					ease enter data.
Screening	Demography - Informed consent	RPTEST					ease enter data.
Screening	Demography - Informed consent	RACE					ease enter data.
Screening	Demography - Informed consent	DMPER					ease enter data.
Screening	Demography - Informed consent	VSDAT					ease enter data.
Screening	Demography - Informed consent						urement is before Date of written Please check.
Screening	Demography - Informed consent						surement cannot be in the future,
Screening	Demography - Informed consent	VSORR					ease enter data.



Clinical Statistics: Statistical Methodology and Statistical Analysis Plan (SAP)

- Different possible designs
  - Clinical trials: Non-inferiority, cluster randomized, basket, umbrella, adaptive, platform
  - Epidemiological and translational
- Statistical Methodology
  - Endpoints
  - Design
  - Statistical methods
- Analyses populations
  - Per protocol
  - Intent to treat
  - Modified Intent to treat

More detailed statistical analysis plan

Statistical Analysis and reporting

Data Analysis

Thank You
for your attention

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