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CDASH en Pratique

Réunion du GUF CDISC (10/02/2011 - Chilly-Mazarin)

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10/02/2011

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CDASH

- **C**linical **D**ata **A**cquisition **S**tandards **H**armonization.
- La collecte des données à la différence de SDTM.
- Pour les personnes impliquées dans la collecte, « nettoyage », assurance de l'intégrité des données de l'essai clinique : Data Manager, Programmeurs, investigateurs, ARCs, CRC, etc…
- Les domaines de CDASH :

Adverse Events (AE)
Inclusion and Exclusion Criteria (IE)
Comments (CO)
Laboratory Test Results (LB)
Prior and Concomitant Medications (CM)
Medical History (MH)
Demographics (DM)
Physical Examination (PE)

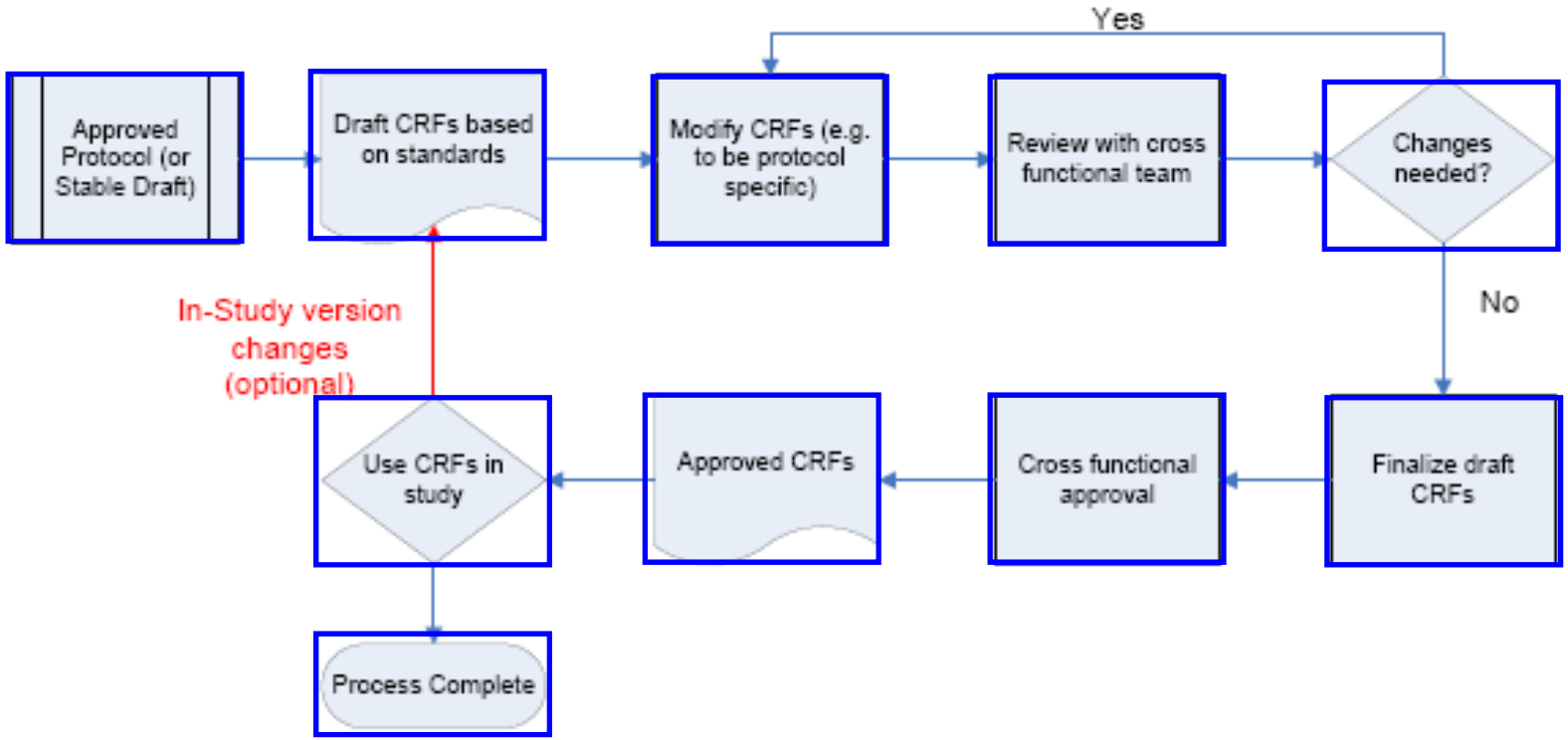
Disposition (DS)
Protocol Deviations (DV)
Drug Accountability (DA)
Subject Characteristics (SC)
ECG Test Results (EG)
Substance Use (SU)
Exposure (EX)
Vital Signs (VS)

Bonnes Pratiques

- Eviter la redondance des données, et se concentrer sur les données importantes.
- Revue de CRFs par les acteurs de l'essai clinique (équipe clinique, biostatisticien, data managers, programmeurs, etc…
- Suivre un process contrôlé dans le design, revue, etc…
- Utiliser les standards.
- Poser des questions claires sans ambigüité.
- CRF Completion Guidelines




CRF Workflow



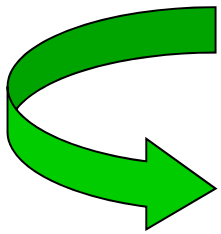
La structure de la table CDASH

	Question Text	Prompt	SDTM or CDASH Variable Name	BRIDG	Definition	CRF Completion Instructions	Information for Sponsors	Core
3	What is the site identifier?	Site	SITEID	StudySite.identifier	Unique identifier for a site within a study.	Record your clinical site's identifier as defined by the sponsor.	**Paper:** This is typically pre-printed in the header of each CRF page for single site studies. For studies with multiple sites, this field is typically left blank so that the number can be recorded by the site. **EDC:** This should be pre-populated. SITENO has been deprecated in CDASH v1.1 and should no longer be used, because SDTM IG V3.1.2 has changed the SITEID variable definition to require uniqueness only within a study, and not within the submission.	HR

- ✓ **Highly Recommended (HR) : Studyid, siteid, subjid**
- ✓ **Recommended/Conditional (R/C)** : brthmo, brthdy
- ✓ **Optional (O) : Sponsor, usubjid,..**

Structure Normaliséé / Dé-normalisée

- Comme SDTM, le CDASH recommande une structure de données normalisée.
  - ✓ Normalisée : une variable pour le test, et une pour le résultat
    - VSTEST, VSORRES
  - ✓ Dé-normalisée : une seule variable par test
    - Height, weight, ...



Structure dé-normalisée => utiliser le préfixe CDASH

Vital Signs

DATE OF ASSESSMENT (dd/mm/yyyy) |_|_| |_|_| |_|_|_|_|

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BODY WEIGHT	HEIGHT	BODY SURFACE AREA
|_|_|_|•|_| kg	|_|_|_| cm	|_|•|_|_| m^2
RECTAL EQUIVALENT TEMPERATURE	**BLOOD PRESSURE (mm Hg)**	**PULSE (beats/min)**
|_|_|•|_| °C	(Sys) |_|_|_| / |_|_|_| (Dia)	|_|_|_|

5.18 Vital Signs – VS (Findings)

Many VS CRFs collect each unique result in its own field (e.g., height, weight, blood pressure, etc.) and the resulting values are stored as separate variables in the clinical data management system. The SDTM IG VS domain utilizes a normalized data structure, i.e., one variable, VSTEST, is used to capture the test name and another variable, VSORRES, is used to capture the result (one record per test rather than one variable for each test). Vital signs are presented as a normalized structure in the domain table, but implementers using a de-normalized structure (one variable for each test) should create variable names using CDISC Controlled Terminology (VSTESTCD).

	Question Text	Prompt	SDTM or CDASH Variable Name	BRIDG	Definition	CRF Completion Instructions	Information for Sponsors	Core
1	Were vital signs collected?	Vital signs collected?	VSPERF	PerformedObservation Result.value	General prompt question regarding whether or not any VS were collected during the study. This provides verification that all other fields on the CRF were deliberately left blank. (NY) (See Section 2.2.)	Indicate if the vital signs were collected. If yes, include the appropriate details where indicated on the CRF.	The intent/purpose of collecting this field is to help with data cleaning and monitoring. See Best Practice Section 3.4, FAQ #6. **For the SDTM-based dataset**, SDTMIG variable VSSTAT is derived from a "No" value in VSPERF. This field does not map directly to an SDTM variable.	O

	Question Text	Prompt	SDTM or CDASH Variable Name	BRIDG	Definition	CRF Completion Instructions	Information for Sponsors	Core
2	On what date were the	Date	VSDAT	PerformedActivity .dateRange*	Date of measurements.	Record date of measurements using this	The date of measurement can be derived from a	R/C

Vital Signs

Highly Recommanded (HR)	Recommanded / Conditionl (R/C)	Optional (O)
VSTEST (Test) VSORRES (Résultat)	VSDAT (date) VSTIM (temp) VSTPT *(Planned time point)* VSORRESU (unité) VSPOS (position)	VSPERF (oui/non) VSSPID (n° ligne) VSCLSIG (signification clinique) VSLOC (endroit)




Vital Signs- Normalisés

DATE OF ASSESSMENT (dd/mm/yyyy) |__|__|__|__|__|__|__| VSDAT		
VSTEST BODY WEIGHT VSORRES VSORRESU |__|__|_|_| kg	HEIGHT |__|__|_| cm	BODY SURFACE AREA |_|•|_|_| m^2
RECTAL EQUIVALENT TEMPERATURE |__|•|_| °C	BLOOD PRESSURE (mm Hg) (Sys) |__|_|_| / |__|_|_| (Dia)	PULSE (beats/min) |__|_|_|

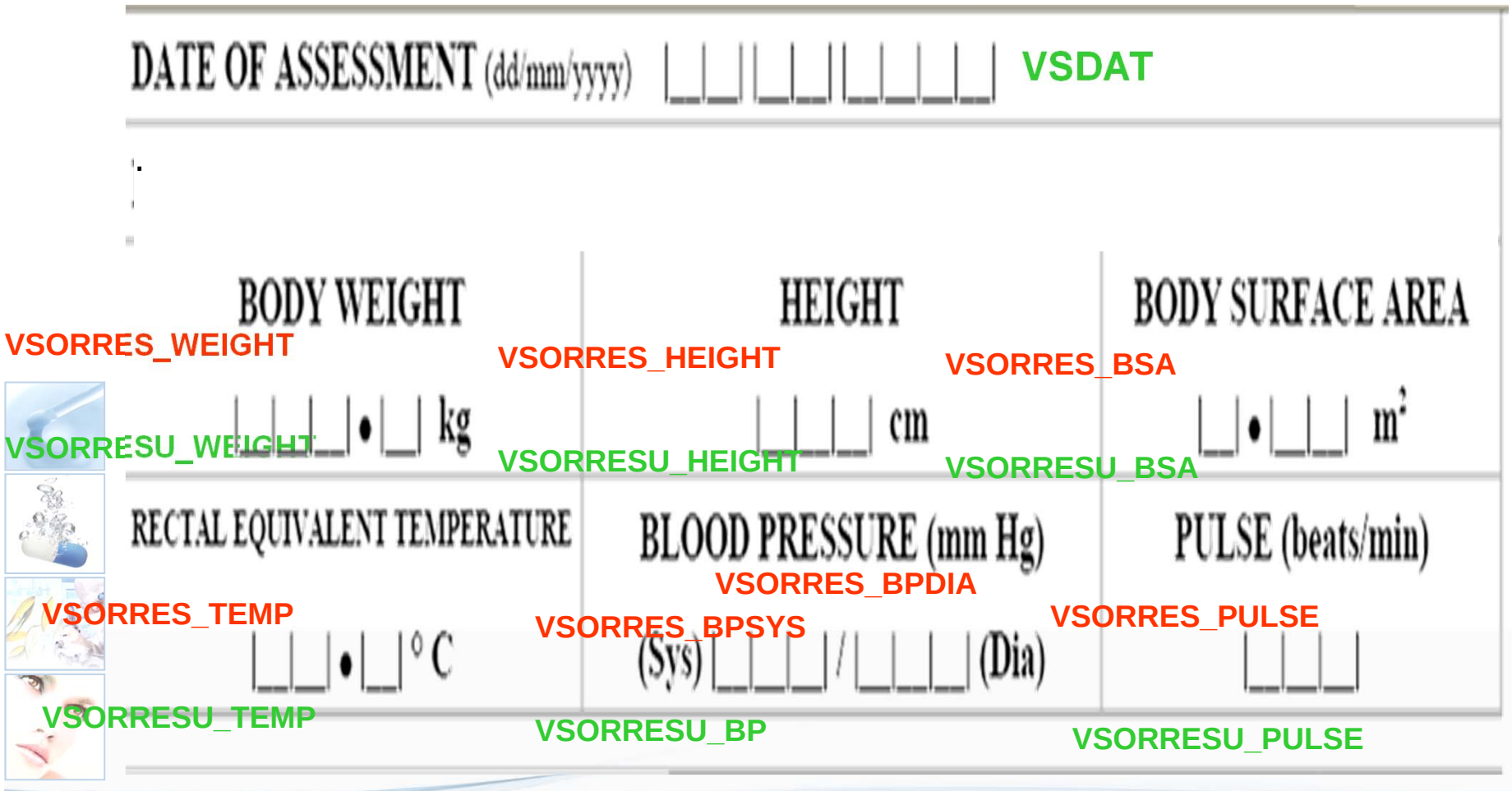



Vital Signs- Normalisés

VSTEST	VSORRES	VSORRESU	VSDAT
PERFORMANCE STATUS	XXX	%	DD-MON-YYYY
BODY WEIGHT	XX.X	KG	DD-MON-YYYY
HEIGHT	xxx	cm	DD-MON-YYYY
BODY SURFACE AREA	xx	m2	DD-MON-YYYY
TEMPERATURE	xx	C°	DD-MON-YYYY
BLOOD PRESSURE_SYS	xx	mmHg	DD-MON-YYYY
BLOOD PRESSURE_DIA	xx	mmHg	DD-MON-YYYY
PULSE	xx	Beats/min	DD-MON-YYYY




Vital Signs- Dé-Normalisés



Vital Signs- Normalisés

VSDAT	VSORRES_WEIGHT	VSORRESU_WEIGHT	VSORRES_HEIGHT	VSORRESU_HEIGHT	VSORRES_BSA	VSORRESU_BSA
DD-MON-YYYY	XX	KG	XXX	cm	XX	m2

VSORRES_TEMP	VSORRESU_TEMP	VSORRES_BPSYS	VSORRES_BPDIA	VSORRESU_BP	VSORRES_PULSE	VSORRESU_PULSE
XX	C°	XXX	XXX	mmHg	XX	Beats/min

Conclusion

- Recommandations pour créer l'instrument de collection des données.
- Mise en place de l'étude clinique et nettoyage des données.
- Facilite le mapping vers SDTM :
  - ✓ Même variables
  - ✓ Structure normalisée
- Ne couvre pas tous les TA.
- Structure dé-normalisée.
- Une bonne base pour commencer un standard.







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