Alliance Global Library and Governance of Standards

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CRF Philosophy

- Defined a minimum set of core functionality
  - Forms needed for trial
  - Target dates on all folders where data is expected via a schedule
  - Required field EC
  - Nonconformant EC
  - Future date
  - Range checks
  - Elig/case eval form
- Built a Global Library containing template forms including both core functionality and additional functionality to enhance efficiency

What is the Global Library?

- The Global Library (GL) is a Medidata Rave tool that facilitates the reuse of study components (e.g. forms, fields, dictionaries, edit checks, derivations, and custom functions) to make study building a more efficient process.

- The Library's Copy Wizard enables users to quickly and efficiently select components stored in the GL and copy those components into project drafts.

What exists in the MCCC/Alliance Global Library?

- General forms (n=58)
- System field edit checks (ECs) (n=324)
  - Queries fire for Required, Non-conformant, Future date/time, and Ranges
  - GL ECs are managed by an EC workgroup
- Configurable ECs (n=309)
- Custom functions (CFs) (n=52)
  - GL CFs are managed by a CF workgroup
- ECs that call CFs (RCFECs)(n=100)
- PRO/QOL forms (n=42)

What exists in the Global Library?

- Standard Enrollment CRFs necessary for all studies utilizing OPEN integrations
  - Step Information
  - Subject Enrollment
  - Demography
  - Treatment Assignment
- Adverse Events CRFs
  - Adverse Events: Baseline
  - Adverse Events: Solicited
  - Adverse Events: Other
  - Adverse Events: Late

What exists in the Global Library?

- Patient Status CRFs (necessary for the navigational CF to function)
- Treatment/Intervention CRF
  - Treatment/Intervention: Dose Modifications, Omissions, and Delay CRF
- Off Treatment CRF

What exists in the Global Library?

- End of Initial Treatment CRF
- Screening CRF
- Case Evaluation CRF
- Eligibility Review CRF

What exists in the Global Library?

- Consent Withdrawal CRFs package
- Lost to Follow-Up CRF
- CTEP Report Variables CRF
- RECIST Measurements: Baseline CRF
- RECIST Measurements CRF

What exists in the Global Library?

- Laboratory Tests and Results CRF
- Concomitant Medications CRF
- Specimen Submission CRFs
- On-Study CRFs
  - On-Study
  - On-Study: Prior Surgery
  - On-Study: Prior Radiation
  - On-Study: Prior Systemic Therapy
- Supporting Documentation CRFs

What is the advantage to using the Global Library?

- Reduces build time.
- Reduces testing time.
- Reduces curation time.
- Reduces cost.
- Provides additional functionality above and beyond the core without adding time and cost.

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Governance of Standards

- Use of template paper CRFs and Paper Case Report Form (pCRF) Guidelines document

- Curator's responsibility to review paper CRFs to assure standards are met before the build in Rave begins

- Use of a Global Library for eCRFs

- Reports available to identify deviations from best practices, naming conventions and standard formats needed for consistent outputs

- Form Builder is used to identify any errors in the PIDs

Curation

- Alliance Curator reviews the paper CRFs before they are built in Rave and identifies any non-standard data elements.

- The eCRF build in Rave is compared to the forms in the FormBuilder tool to assure PIDs, Preferred/Alternate Text, and PVs are equivalent in both systems, where necessary.

QA Checklist Report

- Is run prior to the trial going to production but may be run many times during the life of the Rave build

QA Checklist for A091305
August 26, 2014

Data dictionary entry contains & sign - best to leave a space after it so SAS does not interpret as a macro variable

DataDictionaryName	CodedData	UserDataString
Country_C_PID2018396_V1_0F	HM	Heard & McDonald Isl.
Country_C_PID2018396_V1_0F	PM	St. Pierre & Miquelon
Country_C_PID2018396_V1_0F	SJ	Svalbard & Jan Mayen Isl.
Country_C_PID2018396_V1_0F	TC	Turks & Caicos Islands
Country_C_PID2018396_V1_0F	TT	Trinidad & Tobago
Country_C_PID2018396_V1_0F	VC	St. Vincent & Grenadines
Country_C_PID2018396_V1_0F	WF	Wallis & Futuna Islands
PayMethod_PID2015169_V2_4F	MILITARY SPONSORED (INCLUDING CHAMPUS &TRICARE)	MILITARY SPONSORED (INCLUDING CHAMPUS &TRICARE)
SpecType_PID2018863_V1_0F	H&E slide	H&E slide
N = 9		

QA Checklist Report

QA Checklist for A091305
August 26, 2014

Dictionary field with specify option:
Required field edit check AND Non-conformant field edit check both used
- user will get 2 queries if specify option selected but no specify text entered

FormOID	FieldOID	DataFormat	ControlType	DataDictionaryName	IsRequired	QueryNonConformance	DraftFieldActive
ONSTUDYPRISYSTX	PRISYSTXAGTNAME	$100	DropDownList	ssPriAgent_PID2018334_V1_0F	TRUE	TRUE	TRUE
TOXICITY_OTH	TOXXX	10	SearchList	CTCAE403Term_PID3125301_V1_0F	TRUE	TRUE	TRUE
AELATE	TOXXX	10	SearchList	CTCAE403Term_PID3125301_V1_0F	TRUE	TRUE	TRUE
N = 3							

QA Checklist for A091305
August 26, 2014

Record position is not 0 (standard field on a mixed form) - edit check will not run correctly
CHECK STEPS

CheckName	StepOrdinal	FolderOID	FormOID	FieldOID	VariableOID
RCFEC_PKG_NAV_SetCycleNumber_DZTYPEBSL_COMBSL	1		DZ_TYPE_BSL	COMBSL	COMBSL
RCFEC_PKG_NAV_SetCycleNumber_DZTYPETXCFU_COMTXCFU	1		DZ_TYPE_TXCFU	COMTXCFU	COMTXCFU
RCFEC_PKG_NAV_SetCycleNumber_ONSTUDYPRISURG_COM	1		ONSTUDYPRISURG	COM	COM
N = 3					

CheckName	RecordPosition	IsLog	formislog	CheckActive
RCFEC_PKG_NAV_SetCycleNumber_DZTYPEBSL_COMBSL		FALSE	TRUE	TRUE
RCFEC_PKG_NAV_SetCycleNumber_DZTYPETXCFU_COMTXCFU		FALSE	TRUE	TRUE
RCFEC_PKG_NAV_SetCycleNumber_ONSTUDYPRISURG_COM		FALSE	TRUE	TRUE
N = 3				

Miscellaneous

- Alliance is not currently using the Object Cart Importer (OCI) to import forms into Rave
  - Rave is a better form designer tool
  - Standardized coded values are key for consistent outputs and reporting infrastructure at the Mayo Clinic Cancer Center (MCCC) and are not incorporated into the OCI but are in the MCCC GL
- Alliance does utilize coded values to standardize outputs across funding sources and to facilitate reporting needs (examples: CDUS, DSMB, Grants)

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Questions???