



An Approach to Standard Programming in a Clinical Data Repository

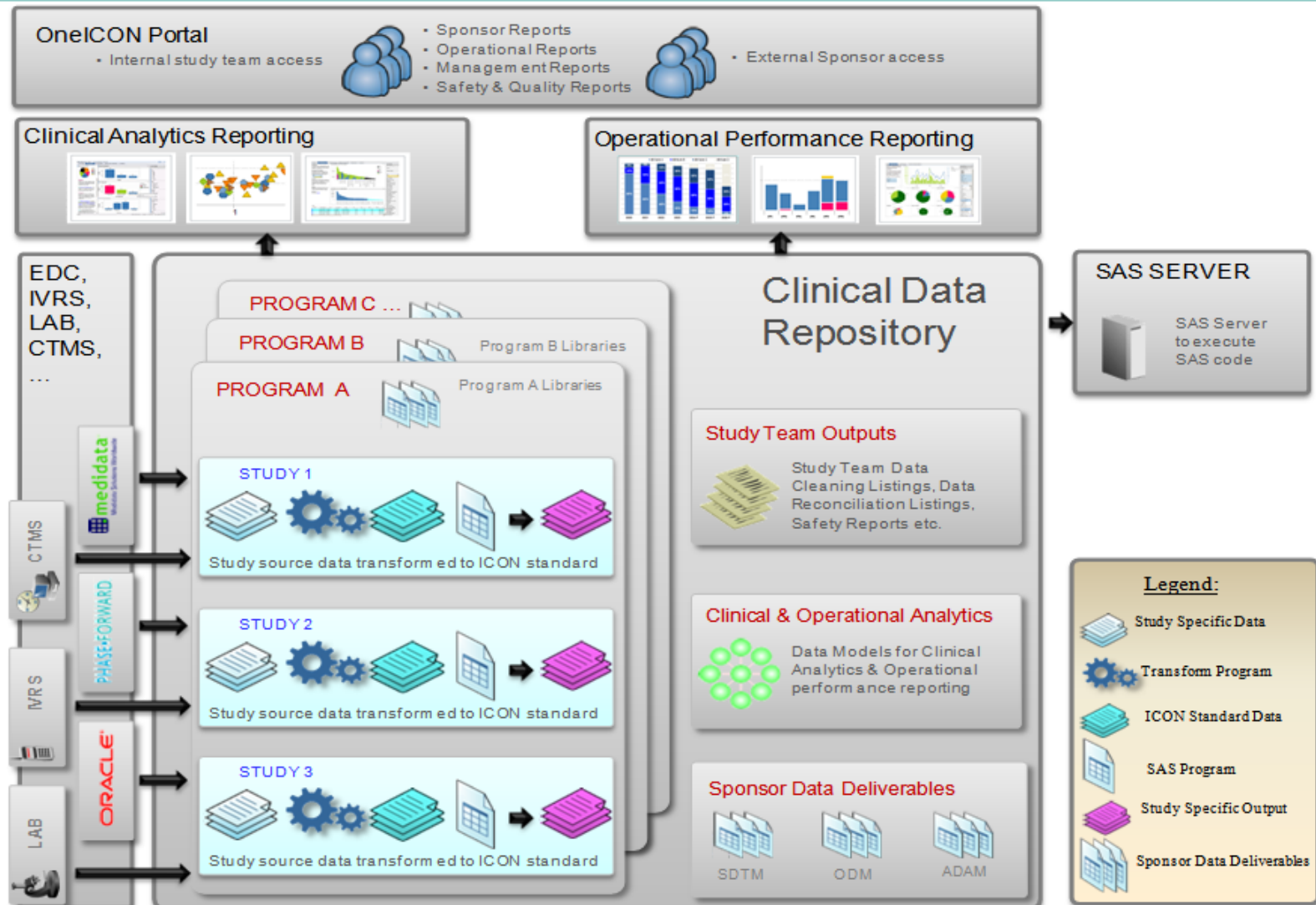
Robert Ellison - ICON Clinical Research plc

- Why Use a Central Data Repository?
- Approach to Standard Code Development
 - Parameter Driven Code
 - Code Template
- Short & Long Term Benefits of Using Generic Code
- Library Maintenance
- Programming Methodology
- Future Developments

Why Use a Central Data Repository?

- Enhance the analysis and delivery of clinical trial data to sponsors
- Produce standardised operational and management reporting assets
- Create a foundation to support clinical data integration and reporting
- Manage trials across data centres

Why Use a Central Data Repository?



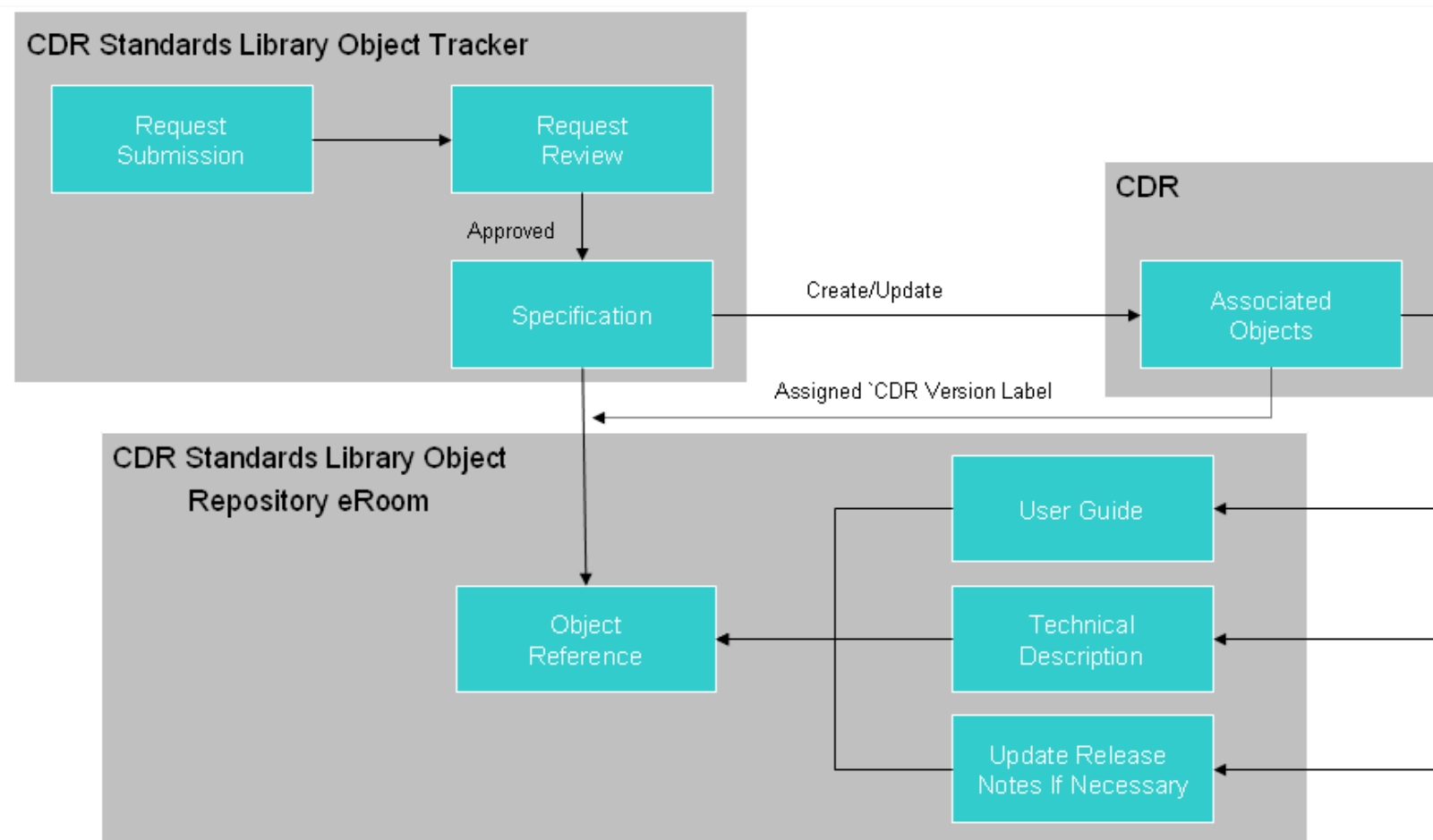
- **Generic Parameter Driven Code**
 - Standard algorithms
 - Fully validated
 - Function/Protocol specific values passed in as parameters
- **Generic Code Templates**
 - Standard Templates for development of Function/Protocol specific algorithms
 - Requires full validation
 - Sections of preprogrammed code integrated with template code
 - Embedded references to generic parameter driven code

- Reduced Programming & Validation Effort
 - For generic and template code
- Standardised Approach to Programming
- Standardised Output Formats
- Reporting Consistently Across:
 - Sponsor
 - Program
 - Therapeutic Area

- **Standard Library Object Tracker**
 - Track the development of all objects in the CDR
 - Maintain a history of objects in the library
- **Standard Library Object Repository**
 - Record details of all objects published in the CDR
 - Tool for programmers to identify code by function in the library

The Standard Library Object Tracker and Repository are linked by a unique object reference number

Library Maintenance



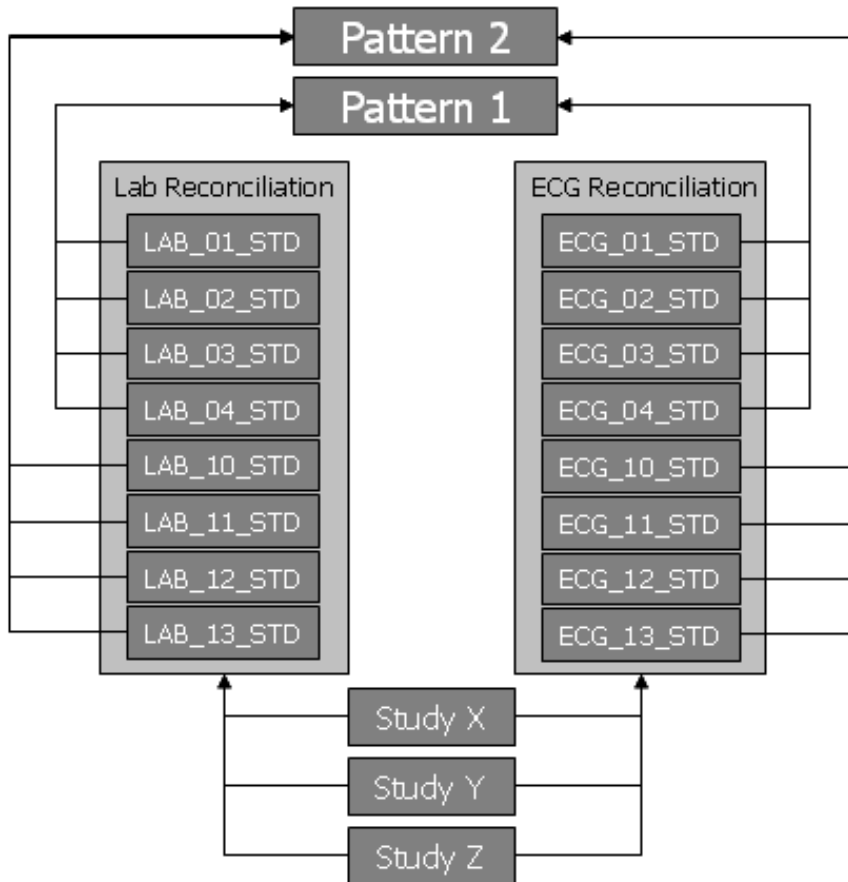
Standard Check Name	Study Specific Check Name	Check Description
LAB_01_STD		List any Subject Number [SUBJID] present in clinical database but does not exist in External data file
LAB_02_STD		List any Subject Number present in external data file but does not exist in Clinical database [SUBJID]
LAB_03_STD		List any Site Number [SITENO] present in clinical database but does not exist in External data file
LAB_04_STD		List any Site Number present in external data file but does not exist in Clinical database [SITENO]
LAB_10_STD		Date of lab sample at Visit X in the clinical database does not match date of lab sample at Visit x in the external file
LAB_11_STD		Gender recorded in clinical database does not equal gender listed in external data file for patient x
LAB_12_STD		For US patients only: Date of Birth [BRTHDAT] recorded in clinical database does not equal Date of Birth in external data file for patient x
LAB_13_STD		For EU patients only: Age [AGE] recorded in clinical database does not equal Age in external data file for patient x

LAB_01_STD
LAB_02_STD
LAB_03_STD
LAB_04_STD

Pattern 1: Value from variable A, table X is not in variable B, table Y

LAB_10_STD
LAB_11_STD
LAB_12_STD
LAB_13_STD

Pattern 2: Value from variable A, table X is not equal to value from variable B, table Y



- Patterns identified within the logic of the program specifications translated into two parameter driven macros.
- Standards Object Repository checked for existing code.
- Existing code incorporated into study specific calling program
- If code does not exist macros developed in the library environment
- Once standard macros are in place in the published domain they can be utilised for the any study requiring same functional outputs.

Future Developments

Clinical Research

Site Details

Number	Name	Current status	Country	Principal Investigator	Lead Monitor
016	Metabolic Research Institute	Initiated	United Kingdom		

Subject Details

ID	Randomization Date	Sex	Age	Race
1602	12-Mar-2009	Female	65	White (Specify)

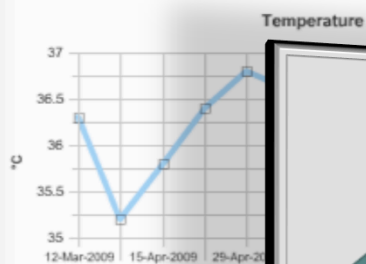
Completed Visits

Name	Date
SCREENING	12-Mar-2009
VISIT2	08-Apr-2009
VISIT3	15-Apr-2009
VISIT4	22-Apr-2009
VISIT5	29-Apr-2009
VISIT6	05-May-2009
VISIT7	14-May-2009
VISIT8	10-Jun-2009
VISIT9	29-Jul-2009
VISIT10	25-Aug-2009
VISIT11	30-Sep-2009

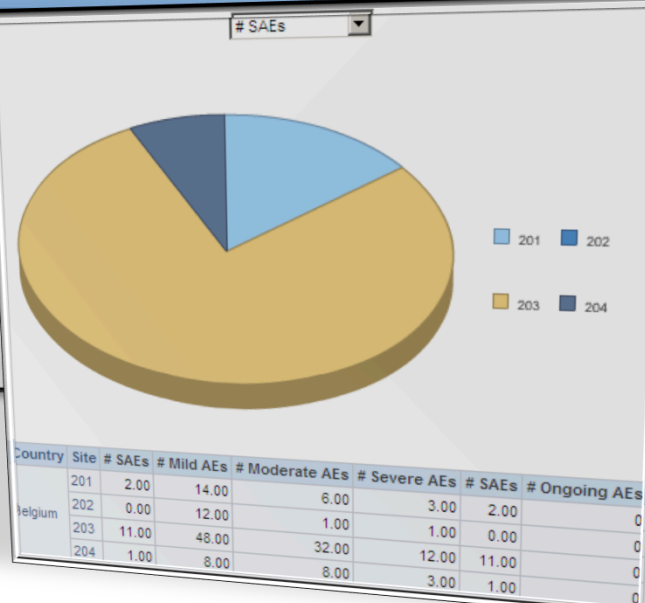
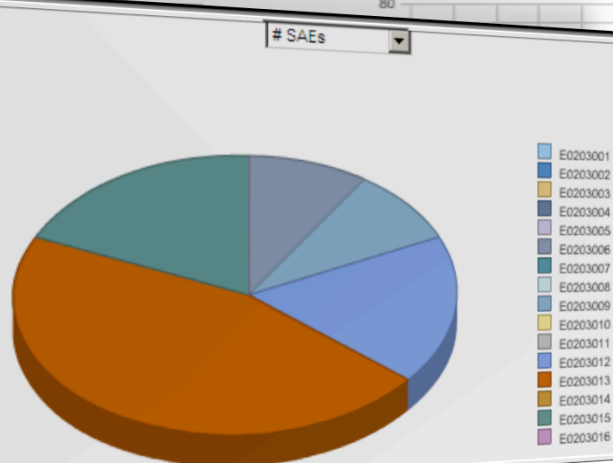
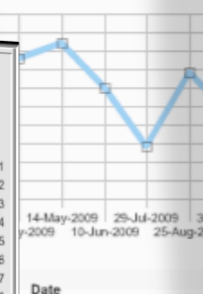
Adverse Events

AE Term	Start Date	End Date	Severity	Causality	Status
VISIONIMPAIRMENT			Mild		Not Recovered
EDEMA BILATERAL FEET			Mild		Not Recovered
Gastric Esophageal Reflux Disease			Mild		Not Recovered
DRUG ALLERGY TO PENICILLIN			Mild		Not Recovered
skin lesions on chest		05-Jun-2009	Mild		Recovered
Postmenopausal			Mild		Not Recovered

VITAL SIGNS



Heartrate



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Clinical Research