

Designing CRF objects to map directly to the GLIB objects in Oracle Clinical

CROs & Small Companies

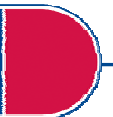
OCUG 2007

Young Rok Chang



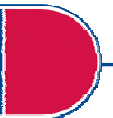
Scope

- With every CRF object that is created, there must be an associated GLIB object that correlates with it. When you design your Case Report Form (CRF), you have to think about how Oracle Clinical (OC) objects are structured.



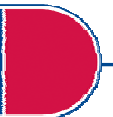
Agenda

- Case Report Form
- Data Standards
- Global Library (GLIB)
- Examples
- Q & A



What is a CRF?

- Case Report Form is defined as
 - “1. A printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor for each trial subject.
 2. A record of clinical study observations and other information that a study protocol designates must be completed for each subject.”



CRF Example

DEMOGRAPHY:

DATE OF BIRTH (dd-MMM-yyyy): - -

SEX: (1) Male
 (2) Female

HEIGHT: (1) in
 (2) cm

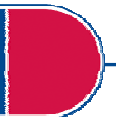
WEIGHT: (1) lb
 (2) kg

RACE: (1) White
 (2) Black
 (3) Asian
 (4) Other (specify "Other")

A tool to collect clinical study data in a formal standardized way

CRF Creation

- Tools/Applications
 - TeleForm
 - Microsoft Word
 - Quark
 - OC RDC
- Available formats
 - Paper
 - Electronic



Data Standards

- Data Standards
 - A formal concept to ensure consistency throughout the data collection
- Genre
 - Internal Standards
 - company - project team, division, group
 - Client's standards
 - each client has different standards
 - Global standards
 - for example CDISC



Pros and Cons between these standards

Pros

Standards - you can improve upon;
efficient; unity

Client's - don't need in house
standards;

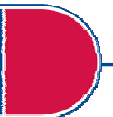
Global - very organized; system
interoperability ; recognized throughout
the industry

Cons

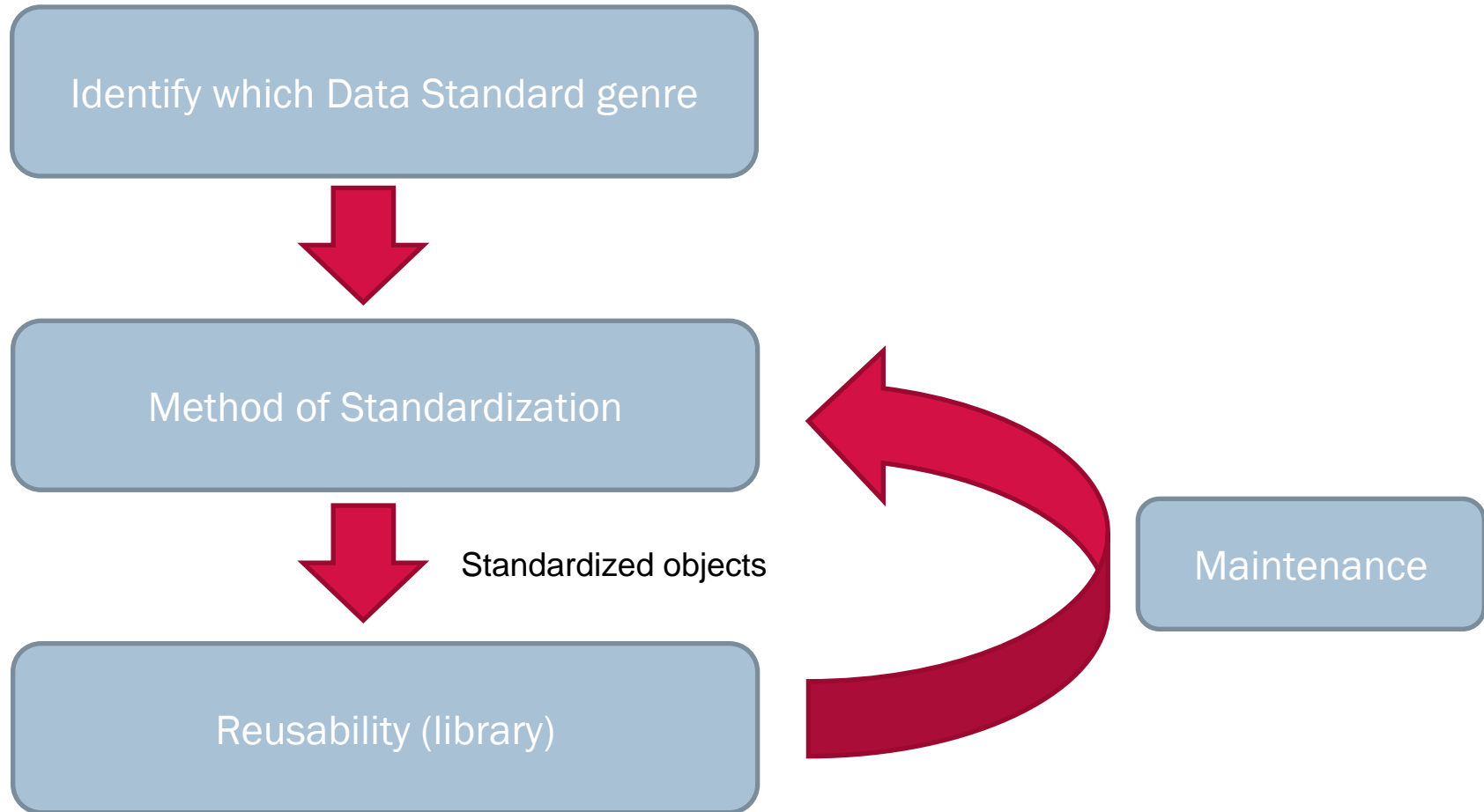
Standards - process could be time
consuming

Client's - you can't improve upon;
training needed; time consuming

Global - training needed;



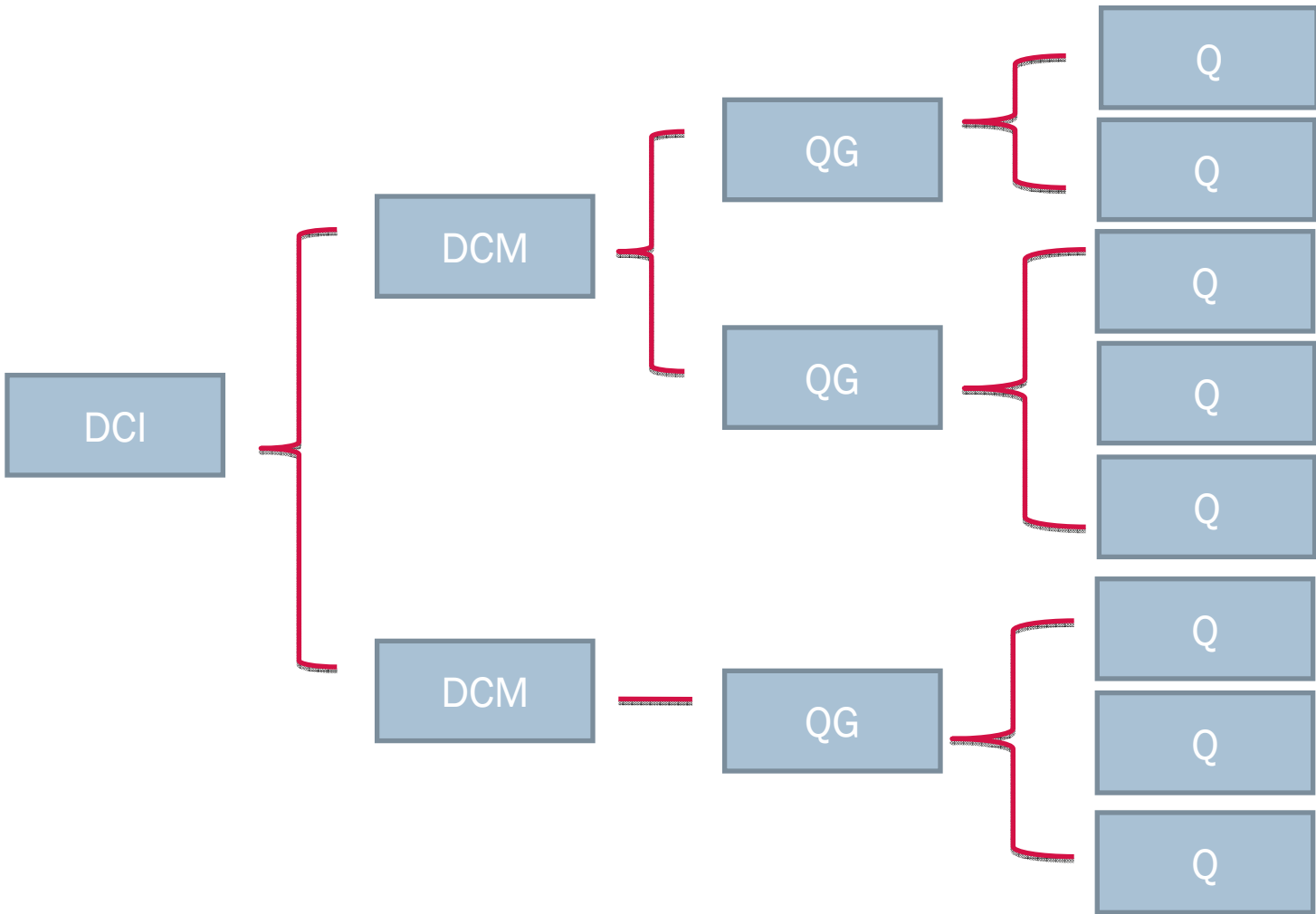
Standardizing CRFs



Global Library (GLIB) - Structure

- Global Library is a storage of standardized objects for Oracle Clinical
- Separated by domain
- Within the domains there are Oracle Clinical Objects
 - DCIs, DCMs, QGs, Questions...

General Structure



Global Library – structure

DEMOGRAPHY:

Questions

DATE OF BIRTH: (dd-MMM-yyyy) - -

SEX: MALE
 FEMALE

HEIGHT: IN **QG**
 CM

WEIGHT: LB
 KG

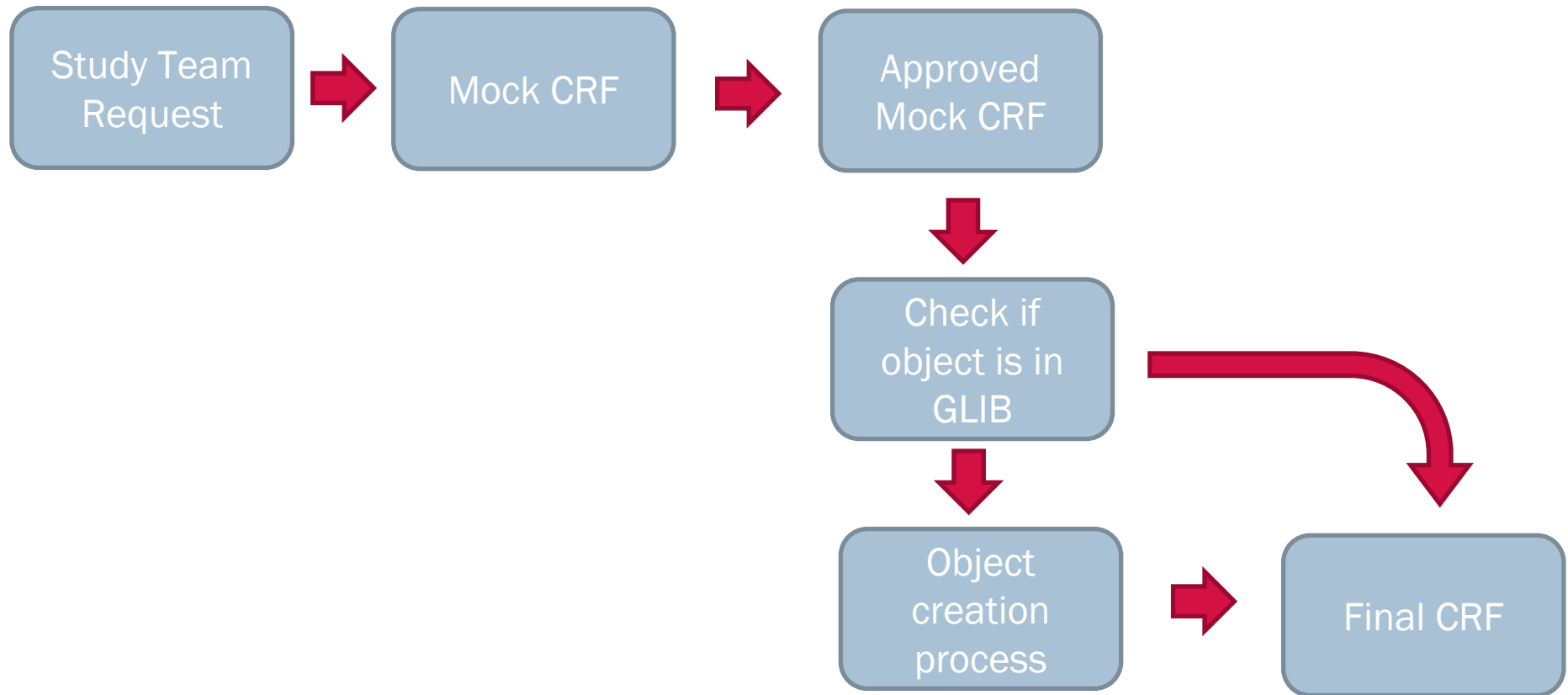
RACE: WHITE
 BLACK
 ASIAN
 OTHER (specify "Other")

DCI **DCM 1**

DCM 2, QG, Q

CHILDBEARING POTENTIAL: If the subject is female is she of childbearing potential?
 YES NO

Implementing objects



Tips on implementing

- After you have approved objects you should mimic the CRF and Glib layouts as close as possible.
- Following the layout closely resembles OC's GLIB structure
- REUSE objects as much as possible

Example

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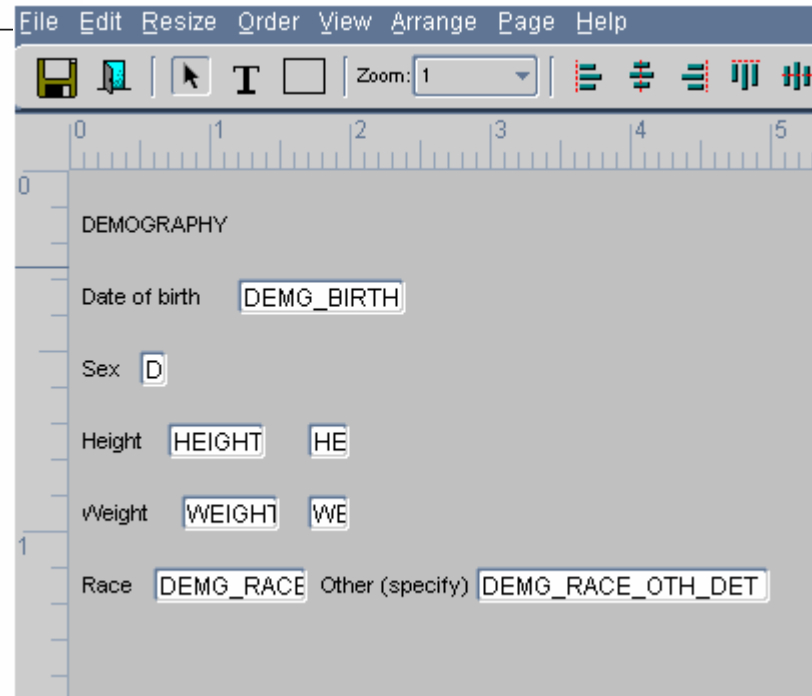
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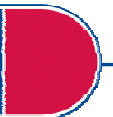
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Conclusion

- When you design your CRF from OC glib objects, make sure you know:
 - OC structure
 - Data Standards
 - CRF layouts versus DCM layouts
 - DE guidelines
 - QC/QA



QUESTIONS?

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