

Readying Business Processes for Oracle Clinical

*“A Phantom ...
...or a Menace? !”*

Steve Burman, Pfizer Inc.

Achim Reeb & Bob Masterson, PROsys LLC



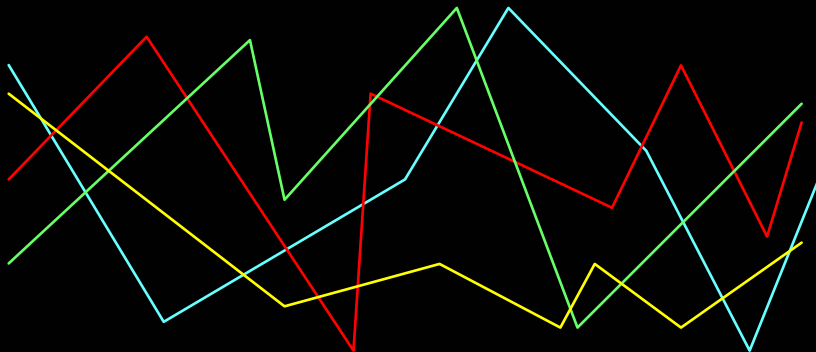
While The Departmental Managers Endlessly
Debate This Alarming Chain of Events,...
The Supreme Business Process Architect
Has Secretly Dispatched Two Jedi..
Business Process Consultants,.....
Guardians of Galactic Peace And Justice,
To Settle The Conflict.....

The Old Conflict...

A Long Time Ago In A Galaxy Far, Far Away...

**Turmoil Has Engulfed The Corporation.
Processes For Data Management
In Outlying Regions Are In Dispute...**

Study Design and Data Management Processes



Different processes and standards meant:

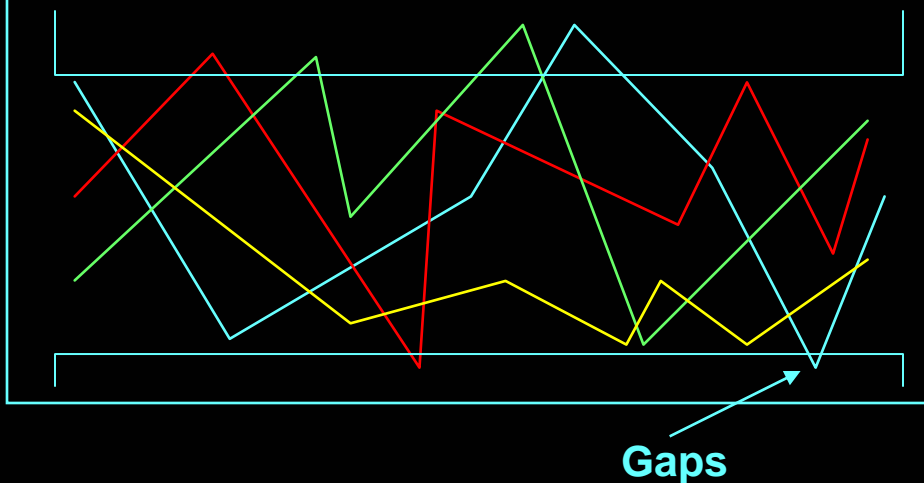
- Data hand-offs caused rework
- No consistency in information storage
- Resources could not be allocated across projects / sites
- “Local” standards were repeatedly re-defined

The Old Solution...

...Hoping To Resolve The Matter With The
Purchase of a New Data Management System...

but

Bandwidth of Process Variation supported by OC

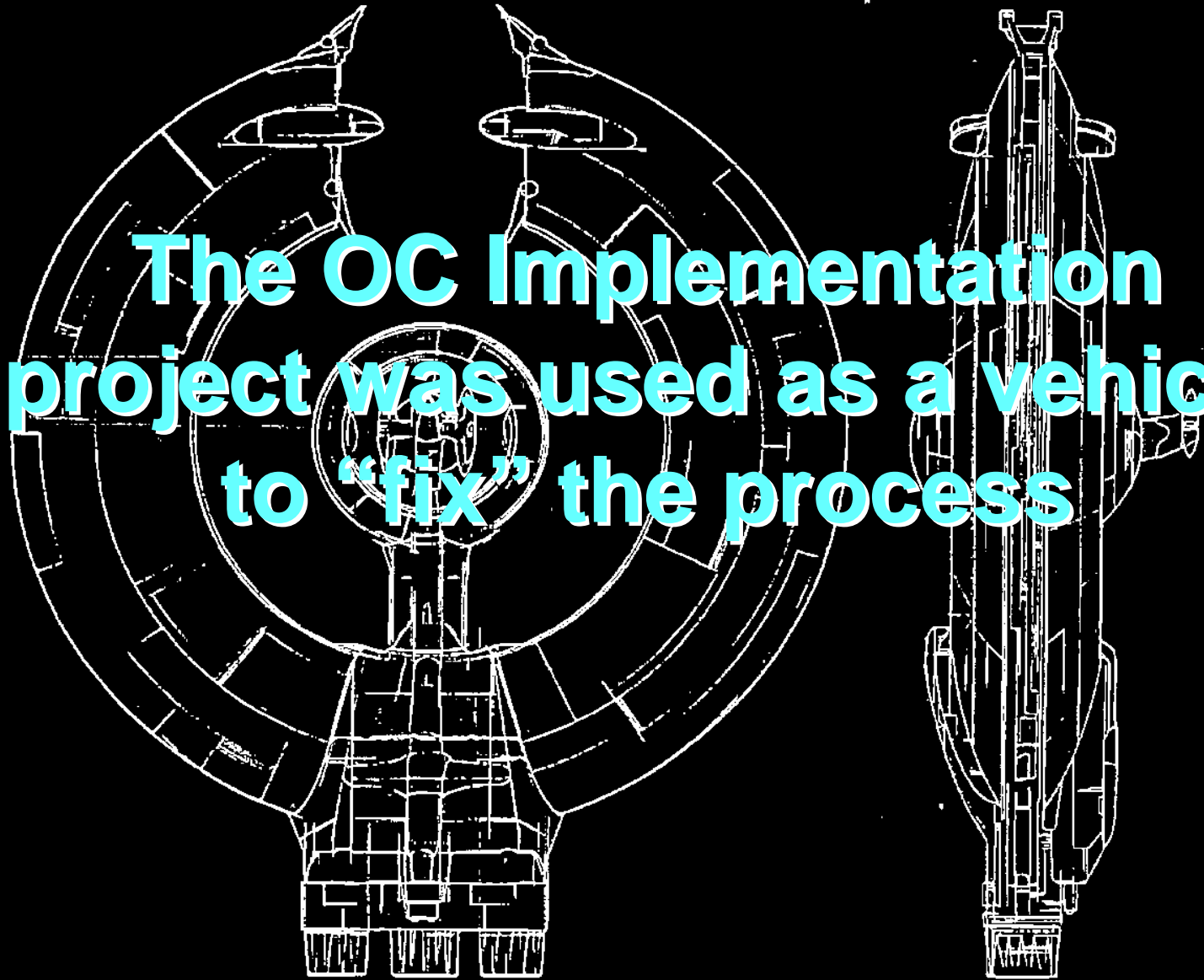


Purchase of a New Data Mgmt System alone would *not* resolve the problem

- OC does not *define* the process
- It is intended to *enable* the process...
- ...As it is the *business* who defines the process based on its particular business needs and objectives

To Settle The Conflict...

The OC Implementation project was used as a vehicle to “fix” the process



Our Mission

From “Study Design” to “Data Extract for Analysis and Reporting”, define process and data standards that:

- 1. Enable us to hand off information between stages in the process, across sites and across divisions, without causing rework**
 - 2. Give us consistency in information storage**
 - 3. Allow flexible resource allocation across projects and sites**
 - 4. Work with the surrounding processes that are not directly supported by OC**
 - 5. Increase the amount of re-usable objects**
 - 6. Take advantage of OC’s functionality**
- **Substantiate the potential business value of a global subject data management process and system**

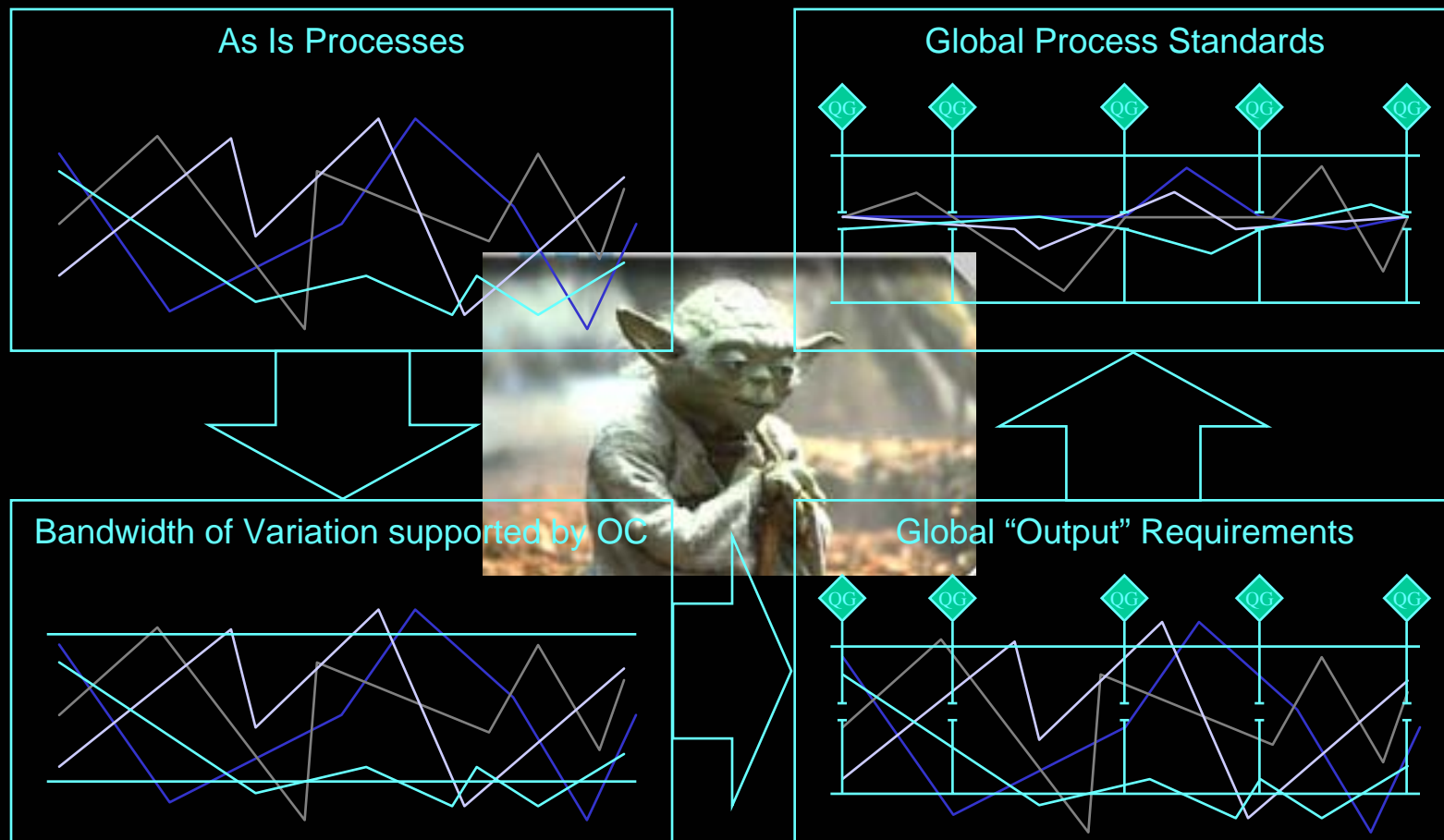
- Get OC up and running so studies can be set up, subject data can be entered and cleaned
- Balance “local” needs and “global” objectives
- Gain cross-functional alignment
- Gain cross-site alignment

The Menace is *not* OC

The devil is in the details of the way the business works



The Approach



- To accomplish the Mission, not every step along the way has to be defined
- At key points, the outputs of the process have to meet global standards

The Deadline

By the way...

...You have 13 weeks to do it

Episode-1

The (Podrace) Workout Approach 1

Divide the Process into “Activity Areas”

- Study Planning & Design (including randomization)
- Study Data Definition
- Data Entry
- Data Validation and Discrepancy Management
- Validation & Derivation Procedures
- Data Extract
- Loading Electronic Data (batch data loader)
- Global library metadata
- System Admin & Security
- Thesaurus and new terms management

Identify knowledgeable “Users” in each site

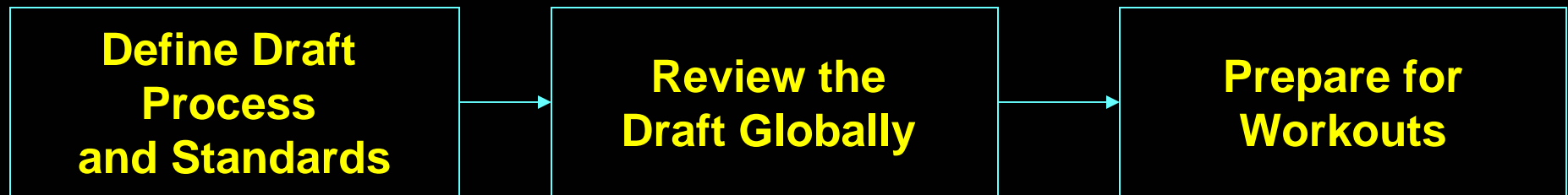
They must know:

- how the business works
- the gaps in OC
- the needs and objectives of the business

Empower a global Group of Users to make decisions

If knowledgeable users from all sites agree that this is the “best” way to work, how can management say “no”?

The (Podrace) Workout Approach 2



One empowered User supported by Jedi

- Identifies:
 - Product Requirements
 - Process Requirements
- Defines Draft Process
- Defines:
 - OC Functions needed
 - Data Standards needed
- Defines products of the process

All empowered Users

- Test, evaluate and discuss draft process and standards in their environment
- Identify site-specific issues with the process and data standards

Jedi apprentices

- Ensure draft process addresses all gaps
- Collect all issues from users
- Regroup the issues
- Plan a facilitated “Workout” session

The (Podrace) Workout Approach 3

- In depth OC training of all empowered users



- Facilitated by Jedi Master
Supported by OC Trainer:
- Review all issues and identify potential solutions
 - Evaluate potential solutions against objectives
 - Agree on global solutions
 - Identify “Out of Scope” issues
 - Identify implementation issues and solutions

Document/Distribute Outcome

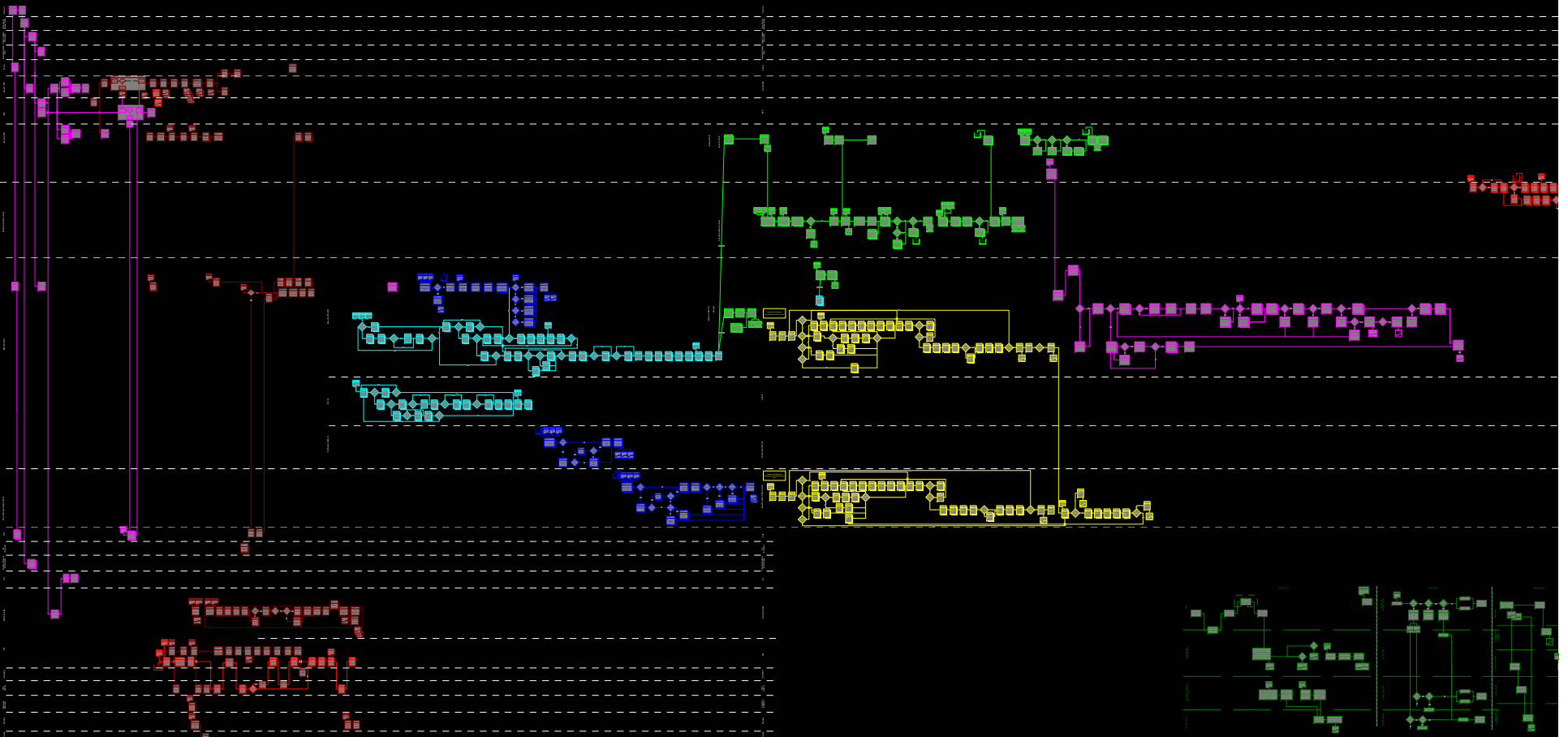
- Jedi apprentices:
- Document agreed processes and standards
 - Document “Out of Scope” and implementation issues
 - Ensure “Out of Scope” issues are addressed in the right Workout session
 - Ensure implementation issues and solutions are consolidated

Integrate Activity Areas

Facilitated Workout with Super-Empowered Users to:

- Fill inter-Workout cracks (unresolved questions)
- Resolve inter-Workout inconsistencies
 - from different Workout teams giving incompatible solutions

The Result

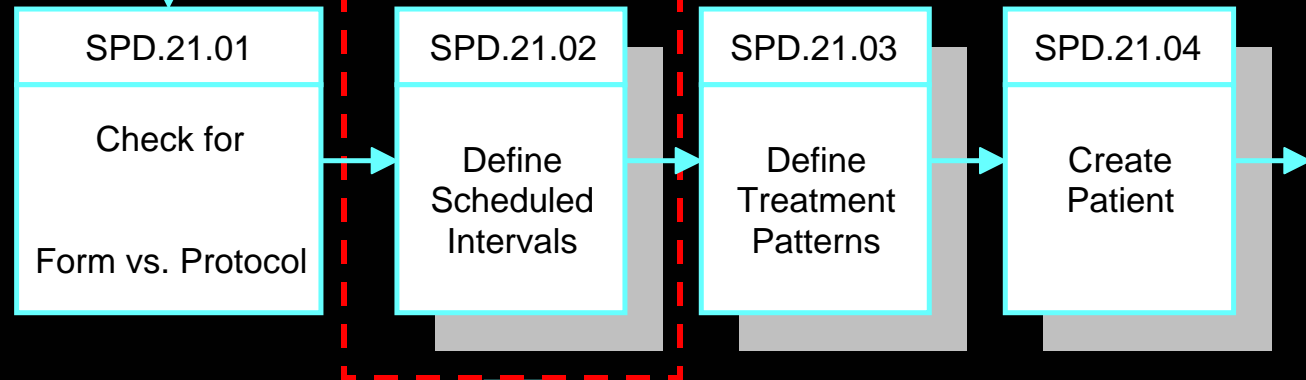


The Detail

Reference Materials for Randomization

| | |
|----------|----------------------------------|
| CPM | Statistician |
| Protocol | Randomization Specification Form |

PROCESS STEP:



MENU PATH:

Design - Studies - Easy Study Design - [Intervals]

SCREENSHOT:



Oracle Clinical 3.1 - OCL 3.1 Beta 2 development - [Maintain Intervals]

Action Move Clear Data Query Special Help Window

Phases for Study MMPFZ_01, Version 1

A

| | |
|------------------|-------------------------------------------------------|
| Phase Name | <input type="text" value="Screen"/> |
| Short Name | <input type="text" value="SCREEN"/> |
| Previous Phase | <input type="text"/> |
| Phase Type | <input type="text" value="SCREEN"/> Screening |
| Time Unit | <input type="text" value="DAY"/> Day |
| Rand Access | <input type="text" value="CLOSED"/> No access allowed |
| Blind Type | <input type="text" value="DOUBLE"/> Double Blind |
| Minimum Duration | <input type="text" value="1"/> |
| Maximum Duration | <input type="text" value="10"/> |

V Randomization Complete Optional ? End Date

Back Save Multi Periods

The name of the Phase
Count: *0



DATA STANDARD:



25

Interval Names

Data Standards:

Phase: example names:

- Screen (Qualifying, before Treatment)
- Test (giving Treatment described in Protocol); may be >1 Test phase.
- (Extension *n*)
- Follow-up (Off-drug)

'Phase' definition: (M = Mandatory fields):

| | | |
|----------------------|---|------------------|
| Phase Name | M | free text |
| Short Name | M | free text |
| Previous Phase | M | OC automatic |
| Phase Type | M | 'F9' list |
| Time Unit | M | 'F9' list |
| Rand Acc Status Type | | OC automatic |
| Blind Type | M | 'F9' list = 'NA' |
| Min to Max Duration | M | free text |

(+ 3 more fields)

- 'Phase Type' and 'Short Name' should be the same, and 'Phase Name' can be used to add more descriptive text if needed.

Period (within a Phase)

- Period 1
- Period 2
- Baseline
- Washout
- etc.

Sub-period (within a Period)

- (not used)

Now What ?

Implementation is more than training in how Oracle Clinical works. It includes:

- **Process-based System Training**
 - These are the steps you go through in the conduct of a trial
 - Here is where you use OC
 - This is how the OC function works
 - This is the screen you see
 - This is where the data comes from
 - These are the data standards you apply
 - This is what you do when things (process or system) don't work
- **Integrated Business and Systems Support**

....and Tomorrow ?

Define a Continuous Improvement strategy that

- **Engages line management**
- **Integrates process improvements and systems improvements / enhancements**
- **Uses the agreed processes and standards, and unresolved issues to generate scripts for testing and evaluating**
 1. New releases of OC
 2. New peripheral systems like Imaging or EDC
 3. Proposals for process changes
 4. Changes in business direction

....Epilogue

Learnings, Conclusions & Undeniable truths

- **Management can say “13 weeks”...**
... but you cannot globally harmonize in 13 weeks if you want to fix the plane in flight
- **A consistent, objective method reduces resistance...**
... and emotions
- **Management needs to lead the army...**
... by investing in future processes as well as current operations
- **The “project” never ends ...**
... that is why it should not be treated as a project, but fully integrated into the way we do business

Questions ?

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Answers!



Readying the Business Process for Oracle Clinical

“A Phantom...or a Menace ?!”

**Achim Reeb and Bob Masterson, PROsys.
Steve Burman, Pfizer Inc.**

Abstract:

When Pfizer Pharmaceuticals set out to replace its patient data management system, the primary driver was the recognition that Pfizer’s business was becoming more global, and its biometrics processes needed to be more efficient, better aligned and better integrated.

After a period of evaluation, Pfizer chose Oracle Clinical as the tool to support and enable its data collection and management processes. Using the PROsys Business Process Framework, Pfizer systematically reviewed every business process directly supported or impacted by Oracle Clinical. Facilitated by PROsys, global teams of Subject Matter Experts from each biometrics activity area defined, agreed and documented process and data standards prior to launching the system. During initial use, a learning support organisation was designed to provide the user with business and technical support, to ensure adherence to agreed process and data standards, and to encourage organizational learning and continuous improvement.

This presentation describes how PROsys Business Process methodology helped Pfizer Pharmaceuticals leverage Oracle Clinical to define and implement the global business processes and data standards, and to achieve the business objectives that originally triggered the selection of this particular system.