



# Generis Consulting Methodology

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# Agenda

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- Independent Requirements consulting
- Generis Project Approach
- Change Management and Lessons Learned
- 'Refreshment' Projects

# Independent Requirements Consulting

## Industry Experience

- Over 20 years working with many of the top life science companies
- Generis consulting 1998 (reg submissions)

## Realising User Requirements

- Different projects have URS documentation in different stages of completion
- Goal is to help realise user requirements, even using another system.

# Generis Project Approach

Activities during the requirements and design stage

The processes during the build stage

The recommended Workshops and CRPs

An outline of Generis' usage of JIRA

Requirements  
and Design

Build

Workshops and  
CRPs

JIRA

# Requirements & Design

## Unique TED Approach

URS → BE → TED → FRS

URS

+

TED

=

No Surprises

Faster Build

Easy FRS

### URS

10.1.57 Within the training workflow, it should be possible to select the available System training groups instead of individual people only

APPROVED

### Business Explanation

10.1.75a We need to select groups as well as users in the training workflow when you send it (EXPECTED)

10.1.75b You should be able to make distribution lists of trainers to send the workflow to (RATHER EXPECTED)

10.1.75c Users should be automatically added to training groups when they complete an XYZ workflow (UNEXPECTED)

### TED

10.1.75a On the initiate workflow screen there will be a pop-up to select recipients. From a drop down you can select both groups of users and individual users. (Example screenshot)

10.1.75b From the tools menu a user can select Distribution Lists and add any user in the system to a personal distribution list. These lists will only appear for the user that creates them, When selecting a group from the drop down detailed in 10.1.75a, the distribution lists that the user has created will appear (Example screenshots)

10.1.75c When any user completes workflow X, there will be an attribute called is\_trained that becomes TRUE. The query that defines the list of recipients in the task template will read this attribute so that when a user initiates a workflow, they may select from trainer users only. (Query and example screenshot)

APPROVED

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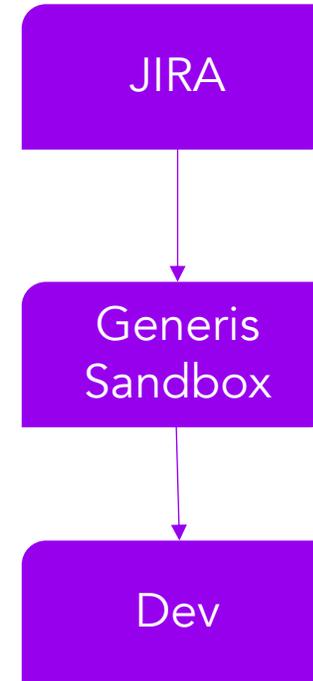
APPROVED

## JIRA, Cloud Sandbox & Dev System

With the Requirements & Design phase complete, Generis will use the approved TEDs in JIRA to configure the system in our cloud-hosted sandbox environment (to which key customer personnel will have access as needed).

We will then transfer the configuration to the Dev environment. Some items like integrations etc. require us to work in the Dev system in order to simulate the customers actual environment, meaning that the configuration will be finalised in Dev.

During the build process we will continue to use JIRA to communicate and track configuration.



# Workshops & CRPs

## Requirements Workshop

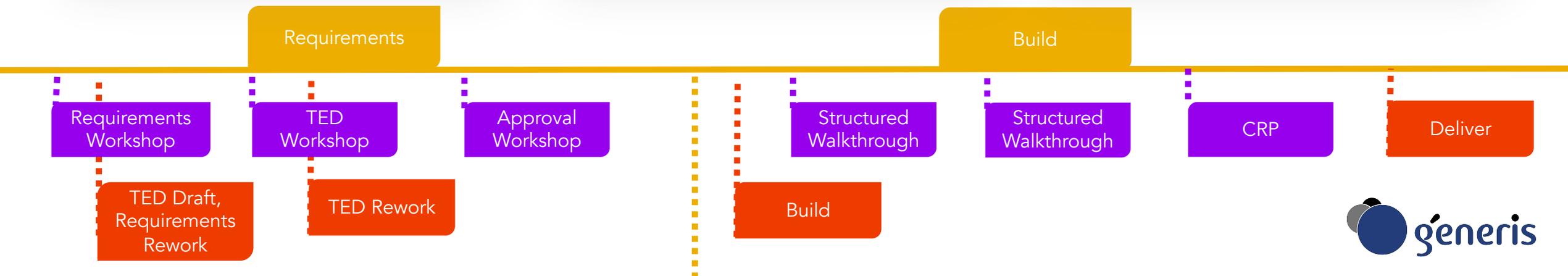
- 2 days
- Developing Business Explanations
- Generis will develop TEDs

## TED Workshop

- 2 days
- Presenting TEDs for feedback
- Address refinements + changes to requirements
- Rework of TEDs

## Approval Workshop

- 1 day
- Generis + Customer present URS, BE and TEDs
- Once approved, Generis begins build



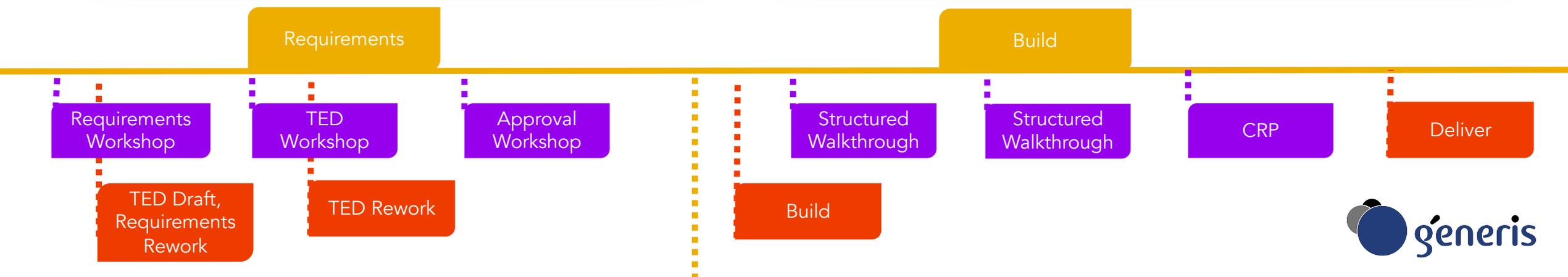
# Workshops & CRPs

## Structured Walkthroughs

- 0.5 Days
- Both reassuring checkpoints and opportunities to see the system in action.
- Remote or onsite
- Generis will demo elements of config
  - E.g. focus may be on workflows

## CRP

- 2 Days
- Occur when the configuration is almost/entirely finalised
- Key users given their first hands-on experience in the system, guided by Generis
- Participants will go through their standard business processes in the new system and become familiar with the functionality.
- Valuable addition to standard training



## Purpose of the Structure

Three different 'spaces' are used in JIRA to manage customer implementations.

### 1. Requirements & Design Project

- In this project, each URS item is uploaded as a separate JIRA item.
- Once TEDs have been approved by customer, their statuses are changed to 'Customer Approved'.
- Both customer and Generis has access to this project.

### 2. Development Project

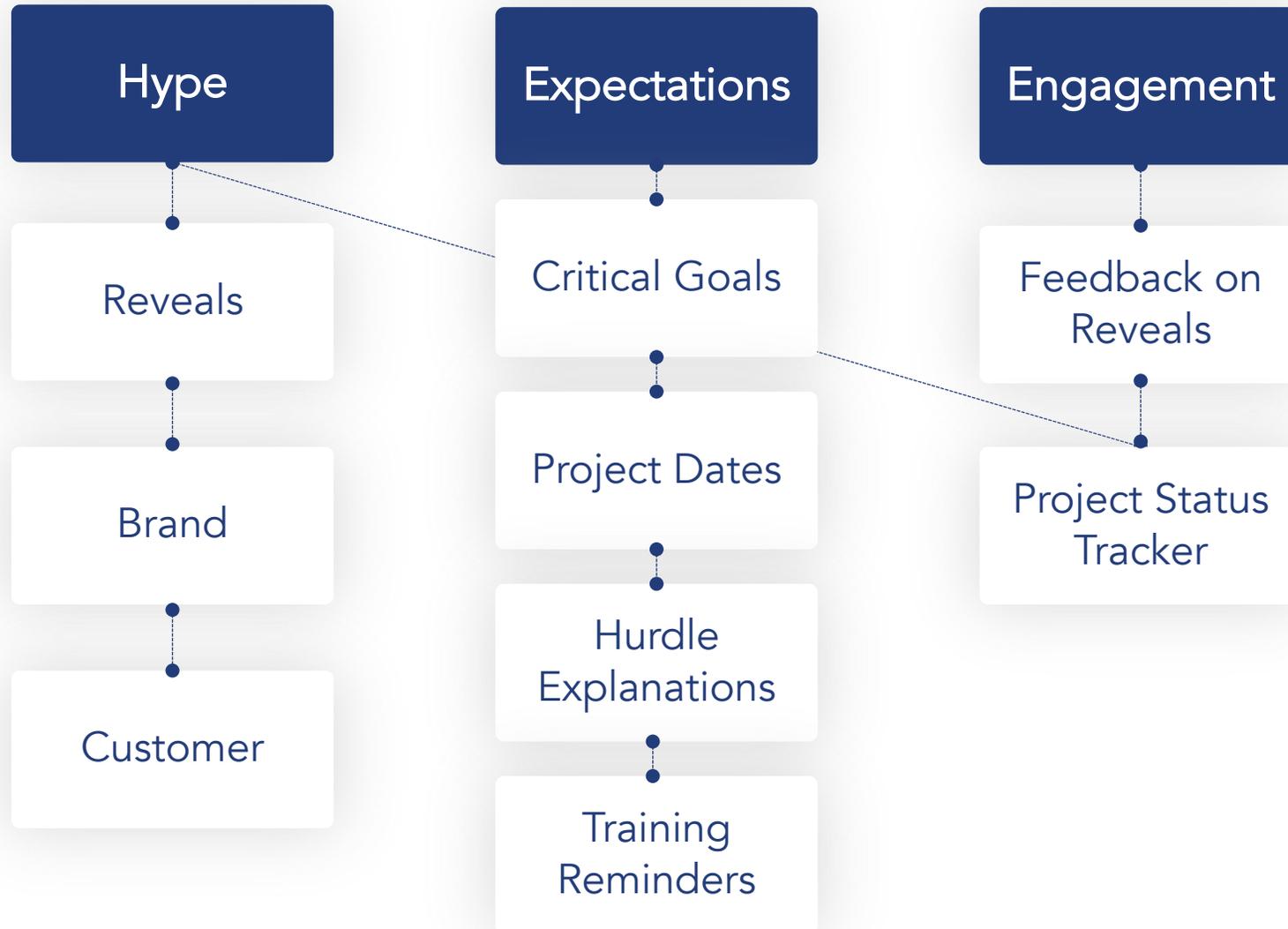
- After a TED is approved, it is duplicated over to the Development project and assigned to a member of the Generis technical configuration team.
- Once configured, the item is marked as 'In Testing' in the Requirements project and assigned to validation staff.
- Once the item has been tested, status is changed to 'Complete' in the requirements project.
- Only Generis staff has access to the development project.

### 3. Workspace Project

- The workspace acts as a communication platform to replace emails and meeting notes. Both parties can log items as questions, follow-up items or tasks and assign them to other project participants. One can attach tickets from the two other projects if one wants to give the recipient more context.

# Change Management

Lessons learned on communication to end user community and initiative owners.





LM Process Stage



## Streamlined Labelling Process in the Next Generation

Dear Colleague,

We're excited to show you the new labelling process that we've created together in action!

[Sign Up to Session](#)

This is a first peek at the new system that is launching in November, so we would love your feedback.

Want to stay more involved?

[Project Status](#)

[Upcoming Reveals](#)



# Refreshment Projects

Considered  
after 3 years

Internal  
Review

IT + Business  
Workshops

Enhancement  
Design

Yes/No

Project Start