CHANGE CONTROL FORM

Change Order (CO) # (if applicable): CO03
Trial Configuration Correction (TCC) # (if applicable): N/A

Version History Table

The first issued Change Control Form will be version 1.0.
If for any reason, an up versioning is required, the new version will be incremented by a full number (2.0, 3.0, etc).

The following abbreviations will be utilized for the Summary of the Update:
A=Add; **E**=Edit; **D**=Delete

Version	Section	Summary of Update	Date Issued
1.0	Initial version	Initial version	29-Aug-2018

Description of Changes and/or Bugs to be Fixed:
(Note: please include the bug# and description of bug, if applicable).

Add delayed verbiage to IDTS for Inform Integration

Level 1 Impact Assessment

To be completed by IRT Design Consultant (IDC) in conjunction with the IRT Project Manager (PM).

Note: For each item, indicate 'Yes' if it is impacted as part of this CCF. **If 'No' or 'N/A' is selected, please indicate a reason in the Reason/Comment field.**

Item	**Reason/Comment** (Note: this field cannot be left blank)
Are Functions impacted? ☐ Yes ☑ No If impacted, list the Functions that will be impacted in the Reason/Comment field: Note: Customer to confirm although this can be provided by Oracle if required.	**N/A**
Are Reports impacted? ☐ Yes ☑ No If impacted, list the Reports that will be impacted in the Reason/Comment field: Note: Customer to confirm although this can be provided by Oracle if required.	**Notifications** (Any written confirmation generated as a result of a transaction): N/A **Alerts** (Any written confirmation generated automatically as a result of a trigger being met): N/A **Reports** (Web reports viewed via the User Interface): N/A
Is the Visit Schedule (as described in the User Requirements Specifications (URS)/Functional Specifications Document (FSD) affected? ☐ Yes ☑ No	**N/A**
Will drug ordering be affected? ☐ Yes ☑ No	**N/A**

Does the change impact any data transfers or integration? ☑ Yes ☐ No Note: Customer to confirm although this can be provided by Oracle if required. Note: If InForm integration is impacted, please contact the Integration Delivery Manager (IDM) and/or InForm PM.	Inform Integration updated
Is there a corresponding data load with this change? ☐ Yes ☑ No Note: Customer to confirm although this can be provided by Oracle if required.	**N/A**
Is there any language impact? ☑ No ☐ Yes (☐ Phone ☐ Web) Note: If 'Yes' please list the number of languages impacted in the Reason/Comment field	**N/A**
Will existing/production data need to be changed? ☐ Yes ☑ No Note: If Yes, estimate how many records are impacted, and indicate this in the Reason/Comment field.	N/A
Is there an extension study being added as part of the CCF? ☐ Yes ☑ No	**N/A**

When adding an extension study onto a core study, is there any impact on the core specific system (such as data integrations / transfers, subject statuses)? ☐ Yes ☐ No ☑ N/A	N/A
Is there an impact on the Roles & Permissions (R&P) Matrix? (ONLY for systems lower than IRT 5.5.6) ☐ Yes ☐ No ☑ N/A	**N/A**
Is there an impact on the System Run-Time Configuration Settings (for IRT 5.5 systems)? Consider data edits and rollback visits. Please highlight if these are impacted by the change. ☐ Yes ☐ No ☑ N/A	**N/A**
Is there an impact on the IRT Configuration Settings Document (for IRT 5.5.6 systems and higher)? Consider data edits and rollback visits. Please highlight if these are impacted by the change. Note: For all other versions of IRT please mark as N/A. ☐ Yes ☑ No ☐ N/A	**N/A**
Is there any impact on documents used throughout the Fast Forward (FF) phase (such as IRT System Maintenance Plan, IRT	N/A

Support Guide, and User Manuals)? ☐ Yes ☑ No Note: if 'Yes', list the impacted documents in the Reason/Comment field. Note: in case of User Manuals, please consider if any translations are needed	**N/A**
Is any change part of this CCF related to a Protocol Amendment? ☐ Yes ☑ No	N/A
If the CCF is related to a Protocol Amendment, can the change be rolled out for all sites concurrently? ☐ Yes ☐ No ☑ N/A	N/A
Is there any dependency/contingency on an existing CCF? ☐ Yes ☑ No	N/A

Documentation Updates

To be completed by IDC:
These specifications must be customer approved prior to Development Start.

Note: For each specification or form, indicate 'Yes' if it is updated as part of this CCF and indicate the version of the document in the Reason/Comment field. **If 'No' is selected, please indicate a reason in the Reason/Comment field.**

Specification or Form	**Reason/Comment** (Note: this field cannot be left blank)
New Protocol version? Note: if 'Yes', indicate the new Protocol version and date in the Reason/Comment field. If a final version is not available at the time of development start the Draft Protocol Memo (FM 301-11) and Final Protocol Memo (FM 301-12) will be created. ☐ Yes ☐ No ☑ N/A	**N/A**
URS/FSD Updated? ☐ Yes ☑ No	**N/A**
Randomization Specifications Document (RSD) Updated? ☐ Yes ☑ No	**N/A**
Data Transfer Specifications (DTS) Updated? ☑ Yes ☐ No Note: Please reference the OCI Secure Data Transmission Policy to verify compliance.	**IDTS PROD v2.0**
Requirements Definition Document (RDD) Updated? ☐ Yes ☑ No	**N/A**
Depot and Drug Ordering Form (DDOF) Updated? ☐ Yes ☐ No ☑ N/A	**N/A**

Manual Transaction (MT) Required? ☐ Yes ☑ No Note: if 'Yes', indicate the MT number in the Reason/Comment field.	**N/A**
Is there an impact on the Roles & Permissions (R&P) Matrix? (ONLY for systems lower than IRT 5.5.6) ☐ Yes ☐ No ☑ N/A	**N/A**
System Run-Time Configuration Settings Updated (for IRT 5.5 systems)**?** ☐ Yes ☐ No ☑ N/A	**N/A**
IRT Configuration Settings Document Updated (for IRT 5.5.6 systems and higher)**?** Note: For all other version of IRT please mark as N/A. ☐ Yes ☑ No ☐ N/A	**N/A**
Review HSGBU.029.FM.002 Services Security Project Checklist per HSGBU.SOP.029 SaaS Services Security Checklist Process ☑ Yes	**N/A**

Level 2 Impact Assessment

Execution Instructions for Impact Assessment

1. Directions for completing the System Development Table

LPD (or designee):

1. Complete the Database Change Only section.
2. Indicate whether the System Design Specifications (SDS)/Technical Design Specifications (TDS) will be updated and list the version # of the SDS/TDS.
3. Indicate whether the SDS/TDS Addendum will be updated and list the version # of the SDS/TDS Addendum.
4. Indicate whether the Code Review, Unit Testing and Integration Testing will be completed.
5. Indicate whether the Audit trail is affected or not.
6. Indicate whether any data transfer including InForm Integration is affected or not.
7. Indicate whether any Subject data is affected or not.

2. Directions for completing the Impact Assessment Table

LPD (or designee)/Test Lead (or designee)/IDC:

1. Include all functions in the Requirements Documents on the Impact Assessment.
2. Determine whether the defined module is ***critical*** or ***non-critical*** based on the following criteria:
    - A change is Critical if a failure to change, or error in making the change, affects any of these:
        1. Patient Safety
        2. Unblinding
        3. Regulatory Compliance
        4. Other Study Integrity Issues (e.g. specific essential data points, critical data transfers/integrations, additional items within the scope that require special handling or consideration but do not fall under categories 1-3).

LPD (or designee):

1. Check section “Changed from Last CCF/Initial Build” as follows:
    a. **Yes** – Module was modified
    b. **No** – Module was NOT modified
    c. **New Function** – Module is new

2. Check section “Type of Change” as follows:
    a. **Cosmetic** – Change to interface (for example, text prompt or skin of interface), change is not critical.
    b. **Prompt** – Change to verbiage played/displayed.
    c. **Minor** – Change affects only that module (for example, change in the workflow, capturing new data, saving different fields in the database).
    d. **Major** – Change affects multiple modules.
    e. **N/A** – Only to be checked in case “Changed from Last CCF/Initial Build” is a New Function.

3. Enter Comments:

- **Critical Functionality** – For new and existing functions marked critical change based on the group assessment completed by the LPD (or designee), the Test Lead (or designee) and IDC above, define in this area any changes that impact critical functionality, including, but not limited to:
    1. Specifics of the Randomization Scheme.
    2. Customizations to Drug Ordering.
    3. Customizations to drug dispensing (including rules for dosing and titration).
    4. Critical dynamic prompts.
    5. Functionality that will impact/display unblinding datapoints.
    6. Other protocol specific change that will have an impact on patient safety or data integrity.

- **Impact on Other Modules** – Provide a detailed description on what other modules are impacted when a change is required for a module. Please note specifically how the modules are affected with any other applicable details.

    NOTE: This "Impact on Other Modules" comment is required for any modified modules regardless of criticality

Test Lead (or designee):

1. Overall Risk / Type of Test: Define the Overall Risk and the Type of Testing required based on the "Changed From Last CCF/Initial Build," "Criticality," and "Type of Change" (if applicable) values:

    a. **Low Risk / Expected Testing**
        1. Criticality (Non-Critical) + Changed from Last CCF/Initial Build (No).
        2. Criticality (Non-Critical) + Changed from Last CCF/Initial Build (Yes) + Type of Change (Cosmetic, Prompt, Minor).

    b. **Standard Risk / Expected Testing**
        1. Criticality (Non-Critical) + Changed from Last CCF/Initial Build (Yes) + Type of Change (Major).
        2. Criticality (Non-Critical) + Changed from Last CCF/Initial Build (New Function).

    c. **Standard Risk / Scenario Testing**
        1. Criticality (Critical) + Changed from Last CCF/Initial Build (No).
        2. Criticality (Critical) + Changed from Last CCF/Initial Build (Yes) + Type of Change (Cosmetic, Prompt, Minor, or Major).
        3. Criticality (Critical) + Changed from Last CCF/Initial Build (New Function).

    d. **N/A / No Testing**

1. In the instance that a change must be made in the development environment and deployed to the Live environment, however, the change cannot be tested in the Test environment as the issue is not able to be replicated in the Test environment.

NOTE: Checking "Scenario Testing" denotes that expected outcome testing (Expected Testing) will also be performed for that function.

2. Enter Comments: Describe any special considerations for impacted functionality as well as specific details in regards to the functionality being tested.

3. Indicate whether Test Plan is updated or not and list the Test Plan version#.

4. Indicate which testing is required: formal testing or no testing.

System Development (LPD)

Database (DB) Change Only: ☐ Yes ☑ No	Note: In case of a critical DB Change Only (as defined in the Impact Assessment section), the Standard Risk Version Release and process is followed. **Description of change** ☐ Adding a country (R4 studies only). ☐ Adding a depot (R4 studies only). ☐ Changing the depot supplier to a country (R4 studies only). ☐ Changing a trigger to an alert. ☐ Adding a role to a protocol (R4 studies only). ☐ Adding/Modifying User Materials (R4 studies only). ☐ Changing limits or other values of the configuration keys specific to production environment and as defined in the StudyConfigVar table (ex. sFTP user/password).

Note: For each item, indicate 'Yes' if it is updated as part of this CCF and indicate the version of the document (if document version is existing) in the Reason/Comment field. **If 'No' is selected, please indicate a reason in the Reason/Comment field.**

Item	**Reason/Comment** (Note: this field cannot be left blank)
SDS/TDS Updated? ☐ Yes ☑ No	**No TDS updates required**

SDS/TDS Addendum Updated? ☑ Yes ☐ No	**None**
Code Review Required*? ☑ Yes ☐ No	**None**
Unit Testing Required*? ☑ Yes ☐ No	**None**
Integration Testing Required*? ☑ Yes ☐ No	**None**
Audit Trail Affected*? ☐ Yes ☑ No	**Audit Trail not affected**
Data Transfer(s) including InForm Integration Affected? ☑ Yes ☐ No	**InForm Affected**
Existing Subject data Affected? ☐ Yes ☑ No Note: if 'Yes', indicate the MT number in the Reason/Comment field.	**None**

* Note: These assessments are preliminary. The actual need for a code review, unit testing and integration testing or whether audit trail is affected will be determined during the development design phase upon approval of this CCF and will be reflected in the appropriate form.

CHANGE CONTROL FORM

LPD Comments: Corection required for delayed verbiage.

Impact Assesment (LPD/Test Lead/IDC)

Module / Tables (Tables are applicable in the case of Database Change Only)	**Criticality** (Refer to rules above for guidance on criticality)	**Changed from Last CCF/Initial Build**	**Type of Change**	**Overall Risk / Type of Test** (please check one)
1. InForm	☑ Critical ☐ Non-Critical	☑ Yes ☐ No ☐ New Function	☐ Cosmetic ☐ Prompt ☑ Minor ☐ Major ☐ N/A	☐ Low Risk / Expected ☐ Standard Risk / Expected ☑ Standard Risk / Scenario ☐ N/A / No Testing
Developer Comments: None **a. Critical Functionality: InForm verbiage** **b. Impact on Other Modules: None**				
Tester Comments: None				

Item	**Version/Reason**
Test Plan updated? ☐ Yes ☑ No Note: If 'Yes', add the version, if 'No', add a reason in the Version/Reason field.	**N/A**
Testing required? ☑ Yes, formal testing ☐ No testing required Note: If 'No', add a reason in the Version/Reason field.	**N/A**

Signature of Test Lead (or designee) indicates this document is accurate in Tester pertinent sections and is accurate and consistent throughout the document to the best of their knowledge.

Comments: (indicate date reviewed if different than date signed)	None
Print Name:	Madhu Thadem
Signature:	DocuSigned by: Madhu Thadem 38358A266C324A1...
Date signed: (must be written, cannot be typed/pre-printed)	03-Sep-2018 | 9:54 PM PDT

Signature of LPD (or designee) indicates this document is accurate in Developer pertinent sections and is accurate and consistent throughout the document to the best of their knowledge.

Comments: (indicate date reviewed if different than date signed)	None
Print Name:	Satish Reddi
Signature:	DocuSigned by: Satish Reddi 05309521B03B4F5...
Date signed: (must be written, cannot be typed/pre-printed)	03-Sep-2018 | 7:44 AM PDT

Signature of IDC indicates this document is accurate in IDC pertinent sections and is accurate and consistent throughout the document to the best of their knowledge.

Comments: (indicate date reviewed if different than date signed)	None
Print Name:	Carly Nickerson
Signature:	DocuSigned by: Carly Nickerson E400E2405F77452...
Date signed: (must be written, cannot be typed/pre-printed)	04-Sep-2018 | 6:50 AM EDT