# Meeting Agenda

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| **Meeting:** | SDTM Quality Assurance Committee Meeting |
| **Date & Time:** | Wednesday, 18-May-2016, 15:00 pm - 15:30 pm |
| **Attachments** | 1. Janssen SDTM Validation Process Manual\_SZ 2. SDTM checklist macros v0 2 (bs) 3. SDTM Validation Programs Zip |
| **Purpose** | 1. Overview of current status of validation programs 2. Set up time table for validation programs / Manual released, and Training delivery |

# **Meeting Participants**

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| **Attendees** | Allen Zeng  Elodie Cheng  Jingjing Yu  Brian Shen  Shenglin Zhang  Annie Xu |
| **Note Taker** | Jingjing Yu |

# Items:

1. **Member introduction (Jingjing: 1 Min)**

Allen Zeng: Update & maintain check programs & Manual

Elodie Cheng: Validate the check programs, create training slide and deliver the training to all Janssen SP

Jingjing Yu: Coordinate, Validate the check programs, and review all

Shenglin/Annie/Brian: Consultant

1. **Basic introduction on Check macros & discussion (Allen 20 Min)**
2. **Introduce on the attachment (Manual, Code, checklist)**
3. **Check programs:**

jjchkmetastd.sas

Jjchkmetadata.sas

jjchksdtmvalid.sas (use checklist: ongoing phase need those points)

jjchkacrf.sas

1. **Question to check with Brian**
2. jjchkother.sas will not be included in this delivery, check with Brian

Reply from Shenglin/Annie: this part could be added after this version.

Allen goes through all check rules first to distinguish ongoing and submission, and discuss in the next meeting

Shenglin will follow up with Janssen for new checklist rule.

1. Check with Brian if add other checks (Brain did in other macros)

Reply from Shenglin: include all checks.

1. Other question for Brian (refer to Janssen issuelog)

XXSTRESC = XXORRES? (Using standard codelist?)

We check xxSTRESC while Sponsor check xxORRES.

Reply from Shenglin/Annie: follow-up

[Brian: except QS, all finding domains use XXSTRESC = XXORRES=standard codelist

Allen will update check programs to check xxORRES]

1. **Next work**
2. Update rule
3. Optimizer program (program header, macro parameters)
4. Fill in more information to Manual
5. **Discuss & Set up timeline (Allen/Elodie/Jingjing 9 Min)**

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| Phase | Start date | End date | Days | Name | Task | Note |
| I (Validation Programs & Manual) | 5/18/2016 | 5/27/2016 | 8 | Allen | (1)    Update checking programs (2)    Refresh ‘Janssen SDTM Validation Process Manual’ per review comment | Elodie/jingjing: could get familiar with these macros, collect issue |
| 5/30/2016 | 6/3/2016 | 5 | Elodie/Jingjing | (1) Validate check programs using dataset (2) Review ‘Janssen SDTM Validation Process Manual’ | Validation & update could proceed paralleled. |
| 6/6/2016 | 6/7/2016 | 2 | Allen | (1)    Update checking programs if any comment (2)    Refresh ‘Janssen SDTM Validation Process Manual’ if any comment |
| 6/8/2016 | 6/13/2016 | 3 | Shenglin/Brian/Annie | Please provide comment on **‘Janssen SDTM Validation Process Manual’** |  |
| 6/14/2016 | 6/15/2016 | 2 | Allen | (1) Update ‘Janssen SDTM Validation Process Manual’ if any comment (2) Re-submit updated version to review until no any comments |  |
| 2 (Training Slide) | 6/6/2016 | 6/8/2016 | 3 | Elodie | Draft ‘Janssen SDTM Validation Training’ based on Manual, including but not limited: how to use and how to review the report |  |
| 6/12/2016 | 6/13/2016 | 2 | Allen/Jingjing | Review training slide and give comment to Elodie |  |
| 6/14/2016 | 6/15/2016 | 2 | Elodie | Incorporate review comment |  |
| 6/16/2016 | 6/17/2016 | 2 | Shenglin/Brian/Annie | Review Training slide and provide comment |  |
| 6/20/2016 | 6/21/2016 | 2 | Elodie | Incorporate review comment and until no more comment |  |
| 3( Release Validation codes/Manual, Deliver Training) | 6/22/2016 |  |  | Elodie/Allen/jingjing | Allen:  (1) Release Janssen SDTM validation programs (2) Release Janssen SDTM validation Manual |  |
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| Elodie: Deliver the training |  |
| 4 (Maintenance) |  |  |  | Allen/Elodie/jingjing | Regular maintain check programs/Manual, and keep users updated |  |
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