Form Revision and Development
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Intent:

• Outline form revision process
• Overview of form changes in 2016
• Revisions for 2017
Form Revision Process
The Process

1. Form Revision Core Team meets with SD of the working committee to determine high level form changes needed.
2. Also identify additional stakeholders/SMEs that may need to review.
3. Announcement sent to network and CIBMTR staff that "open comment period" has begun. Request change suggestions and volunteers.
4. Suggested changes are gathered.
5. Initial Review Committees (IRC) are formed (with help from mngmt and SDs).
6. Includes reaching out to stakeholders/SMEs.
7. All suggested changes, problem areas, etc are compiled.
8. Meeting is held with SDs to review the forms, and identify high level changes needed. Also identify additional stakeholders that need to review.
9. Feedback from SDs is gathered on comments to be reviewed by IRC.
10. Feedback to get right level feedback, and from whom it needs to be reviewed. Feedback to clearly define that this isn’t a detailed review. It’s high level. SD from the related working committee or core team will need to communicate this to the SD group.
11. IRC meetings are held to review feedback.
12. IRC updates comments to be reviewed by IRC.
13. IRC meetings are held to review feedback.
14. IRC updates comments to be reviewed by IRC.
15. Final drafts are created and distributed to IRC members for final review.
16. Forms sent to CIT MKE and CIT MSP representatives for review from the RDB and IDW standpoints.
17. Comments discussed at recurring Thursday meeting.
18. Drafts are distributed for final approval along with a survey to track approval.
19. Feedback is collected and drafts are updated.
20. 24 hour final notice email sent. Any feedback received is addressed.
21. Forms are ready for form entry.

Intended to get high level feedback, and from whom it needs to be reviewed. Feedback to clearly define that this isn’t a detailed review. It’s high level. SD from the related working committee or core team will need to communicate this to the SD group.
Step 1 – Plan Ahead

• Plan what forms to revise and when
  – Form Revision Core Team
  – Draft proposed schedule
  – Scientific directors and senior leaders review and approve
  – Flexible – allow wiggle room for critical revisions, or new priority forms

• Goal had been to revise every 3 years
Form Revision and Development Process

• What forms should be revised next?
  – Several factors:
    • Length of time since last revision
    • Upcoming studies
    • Needed for cellular therapy
    • Necessary updates
Step 2 – Prepare for the Revision

• Prepare!
  – Meet with scientific director of working committee
  – Announce revisions to all scientific directors
  – Announce revisions to network
    • Volunteer!
    • Send form change suggestions
Step 3 – IRC

• Form a revision committee and get started
  – Invite physicians, SMEs, data managers, and other individuals to participate.
  – Group is referred to as the Initial Review Committee (IRC)
# Initial Review Committee (IRC)

<table>
<thead>
<tr>
<th>IRC Members</th>
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<tbody>
<tr>
<td>Form revision coordinator</td>
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<tr>
<td>Scientific director of working committee</td>
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<tr>
<td>Working committee chairs</td>
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<tr>
<td>Subject matter experts (SMEs)</td>
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<tr>
<td>Data managers</td>
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<tr>
<td>CRC representative(s)</td>
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<tr>
<td>Audit team representative</td>
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<tr>
<td>Statistician</td>
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<tr>
<td>Metadata representative</td>
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<tr>
<td>Management representative</td>
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</tbody>
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Initial Review Committee (IRC)

- Meets weekly
- Detailed review of forms
  - Majority of content changes are made here
- Typically takes 2-4 months
Step 4 – CIT Review

• CIT Review
  – Review forms with CIT
  – Help identify validation ideas, potential problem areas, and discuss form development
Step 5 – Scientific Director Review

- Scientific Director Review
  - Form drafts and change summaries are distributed
  - Review occurs at standing meeting
  - Updated drafts sent for approval along with survey to track
  - Final 24 hour notice email sent before considered “approved”
Step 6 – Prepare for Release

Form Entry Life Cycle – Form Entry to AGNIS Release

Form Relation: Business Team
- Final Draft is Approved
- Spreadsheet developed with calculations and events & actions
- Smart navigations and validations are extended into AGNIS. Confirms with FDM
- Check with stakeholders

Metadata Team
- DDC/CDE information is reviewed, created in database
- Field names are reviewed and associated to the fields
- Peer review and resolution issues

FN3 Development
- Development
- QA
- UAT

AGNIS Metadata Team
- New CDEs are created and reviewed
- CDE to FN field name mapping developed
- Mapping spreadsheet generated in AGNIS translator
- Mapping spreadsheet uploaded to AGNIS translator

Audit Team
- Manual Content is Finalized
- Scientific Review
- Stakeholder Review
- CRC Review
- Editor Review

LMS Training
- LMS Development begins
- Scientific Review
- CRC Review
- Stakeholder review and approval
- Final updates include

Process for form getting to retrieval?
Step 6 – Cont’d

• Approved forms are entered into FN3
  – Forms are developed in FormsNet 3
  – Validations are created
  – Events and actions are defined (how forms come due)
  – Many parts to form entry: metadata work, AGNIS, mappings, etc.

• Manuals and eLearnings are updated/developed
• Forms are released!
Additional Steps

• OMB Approval
  – Some forms require OMB approval

  – Can be a long process (6+ months), but there are also exceptions
    • Requires time studies
    • 60 day notice, 30 day notice, review and approval
    • Change request vs. full approval
Form Revision Process Changes

• Lean Project
  – Shorten content review process
  – Goal is 12 weeks

• Try and release less forms more often
  – Quarterly releases

• Modular approach
  – Smaller forms
  – Easier revisions
How to Get Involved

• Submit form change suggestions
  – Can be submitted at any time
  – Send to your CRC
  – All suggestions are reviewed during the next revision

• Volunteer
  – Participate on a form revision committee!
  – Important to have data managers involved
2016/2017 Form Release Highlights
Form Release Highlights

• Summer (July 2016)
  – Pre-CTED 4000
  – Post-CTED 4100
  – Cellular Therapy Infusion form 4006

• Fall (November 2016)
  – CLL 2013/2113
Form Release Highlights

• Winter (January 2017)
  – Pre-TED 2400/2402
  – Post-TED 2450
  – CRF follow-up form 2100
  – Death form 2900
  – HLA Form 2005
  – CML 2012/2112
  – CMS Study Forms 2554-2557
Form Release Highlights

• 2400 Split
  – Split into 2 forms (Pre-TED 2400 and Pre-TED disease classification Form 2402)
  – Very minor content changes
  – Supports modular approach
  – Allow CIBMTR to revise more frequently, with less impact

• Death Form
  – Updated cause of death options
Form Release Highlights

• CRF Form 2100 and Post-TED 2450
  – Harmonized questions between forms
  – Chimerism Form 2451 and Select-TED 2455 merged with 2450
  – 2200 and 2300 were merged with 2100
  – Updates to GVHD, chimerism, infection
  – Reformatted new malignancy questions
  – DCI data now captured on Cell Therapy Forms
Form Release Highlights

• New CMS – Myelofibrosis study forms
  – 16-CMS-MF - Prospective Assessment of Allogeneic Hematopoietic Cell Transplantation in Patients with Myelofibrosis
  – Developed 4 new forms to support the study

  2554 – CMS Registration

  2555 – CMS-MF Eligibility

  2556 – CMS-MF Pre-HCT Supplemental Data Form

  2667 - CMS-MF Post-HCT Supplemental Data Form
Upcoming Revisions
2017

• AML and ALL

• Infection forms
  – Fungal 2046/2146
  – New infection forms
    • Respiratory Viruses
    • CMV/EBV/ADV/HHV-6

• New form features
2017

• Cellular Therapy Forms
  – Tentatively planned for summer release

• Lymphoma
  – Revisions will begin after Tandem

• 2400, 2000, 2006
Thank you!

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Theresa Scoggins
Theresa Amatucci
Yolanda Clay
And many others!