

Overview of New CPI Standards

TCT Clinical Research Professionals / Data Management Track

Wednesday, February 3rd, 2021

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No conflict of interest to disclose

The CIBMTR[®] (Center for International Blood and Marrow Transplant Research[®]) is a research collaboration between the National Marrow Donor Program[®] (NMDP)/Be The Match[®] and the Medical College of Wisconsin (MCW).



Purpose of CPI Program

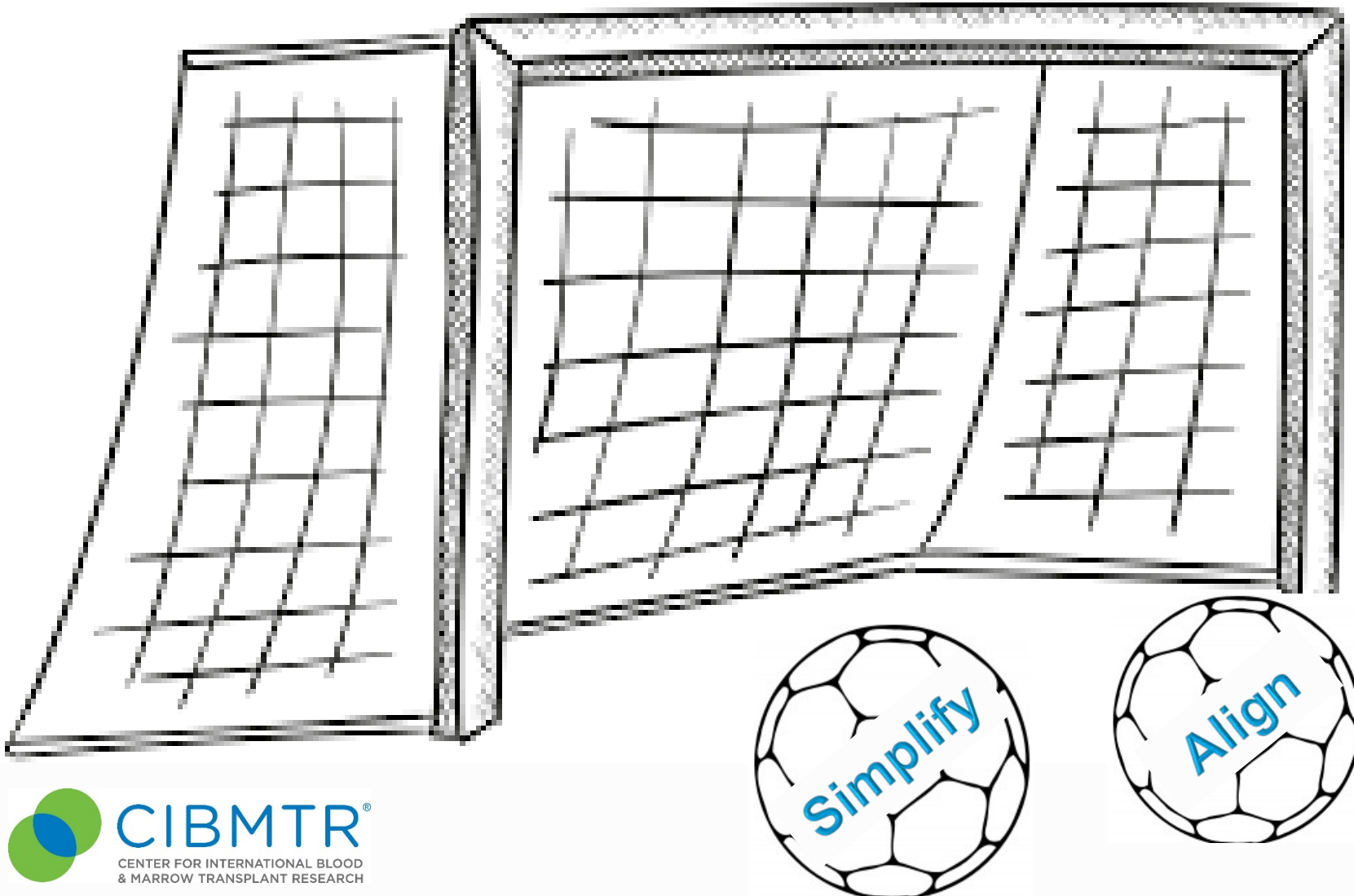
Continuous Process Improvement (CPI) evaluates data completeness and timely reporting at a center level.

- Separate programs for recipient and donor data.

Prioritizing complete / timely reporting is fundamental to all CIBMTR programs and supports registry quality assurance efforts.



Why the Change?



New Requirements



IRB Approval of CIBMTR Consents

1. No lapse in IRB approval during the current trimester
 - If lapse occurs:
 - No patient consented during lapse –OR–
 - All patients re-consented before end of trimester
2. Documentation must be received and approved by CIBMTR by end of Trimester



Consecutive Transplant Audit (same as 2020)

1. Submit list of HCTs performed during previous year
 - All patients must be registered (CRID Exists)
 - All infusions must be reported (at least 2400 DUE)
2. Resolve discrepancies between your CTA list and FormsNet3
3. Resolve queries placed to reprocess forms with incorrect information.



Queries

Resolve **95%** of queries placed during the **Previous Trimester**

Queries are placed for:

- Missing critical data
- Inconsistent data
(mismatch between forms)
- Incorrect overrides/specify fields
- Clarification / confirmation
(de-identified source documents)

Queries support:

- Studies
- Quality Assurance reports for CBB/AC/CC
- CVDR, TCSA, CTA



Form Completion Criteria

Where we're at:

All Forms

HCT
Autologous

HCT
Allogeneic Related

HCT
Allogeneic Unrelated

CT
{all donor types}

Past
Trimester

Year Prior

Everything
Else Prior

Past
Trimester

Year Prior

Everything
Else Prior

Past
Trimester

Year Prior

Everything
Else Prior

Past
Trimester

Year Prior

Everything
Else Prior



Form Completion Criteria

Where we're going:

All Forms



Form Completion Criteria

Where we're going:

All Forms

Critical

On-time
Completion

Past
Trimester



Form Completion Criteria

Critical Forms

- Indication Form 2814
- Pre-TED Form 2400
- Pre-TED Disease Form 2402
- HCT Product Form 2006
- Pre-CTED Form 4000



Form Completion Criteria

On-time Completion

95% of critical forms due during the **Current Trimester** must be completed by the **Due Date**

Past Trimester

98% of critical forms due during the **Previous Trimester** must be completed (*regardless of due date*)



Form Completion: Critical Forms


Did the site get to $\geq 95\%$ critical forms completed by the FN3 Due Date?

- It's December 31st at 11:59pm and we're trying to figure out if Site A has hit their target
- Between October 1, 2020 and December 31, 2020, Site A had **40 critical forms due**
 - They **completed 38 critical forms** by the FN3 **due date**,
 - **1 form after** the **due date**, and
 - **1 form** has **not** been **started**
- ✓ Yep! – 38 / 40 (95%) critical forms by the FN3 Due Date



Form Completion: Critical Forms

Did the site get to $\geq 98\%$ critical forms completed?

- We worked through the prior example so quickly, it's still 11:59pm on December 31st. We need to figure out if Site A hit the **second critical form target**.
 - Between May 1, 2020 and August 31, 2020, Site A had **50 critical forms due**
 - They completed **38 critical forms** by the FN3 **due date**,
 - **9 forms** after the **due date**, and
 - **3 forms** were **not started**
-  Shoot, Missed It! – 47 / 50 (94%) critical forms were complete



Form Completion Criteria

Where we're going:

All Forms

Critical

Study
Supplemental

On-time
Completion

Past
Trimester

Past
Trimester



Form Completion: Study Supplemental Forms

Complete **100%** of forms due during the **Previous Trimester**
(regardless of due date)

When are these forms requested?

- Studies with unique data needs
- Site has committed to participate

Form Examples:

- Mogamulizumab Supplemental Data Collection Form 2542
- Mylotarg Supplemental Data Collection Form 2543



Form Completion Criteria

Where we're going:

All Forms

Critical

Study
Supplemental

Everything
Else

On-time
Completion

Past
Trimester

Past
Trimester

Past
Trimester



Form Completion: Everything Else

Complete **95%** of forms due during the **Previous Trimester**
(regardless of due date)

Form Examples:

- Follow-Up Forms (2450, 2100, 4100)
- Infection Forms (2149, 2150,.....)
- Disease Inserts (2010, 2110, 2011, ...)



Complete List of Updated Metrics

Current Trimester

- No lapse of IRB Approval
- CTA
- 95% completion of critical forms BY FN3 DUE DATE

Previous Trimester

- 100% completion of study supplemental forms
- 98% completion of critical forms
- 95% completion of all other forms
- 95% completion of queries



Rollout / Ramp Up Plan

1

Formally communicate new requirements

2

Send sites info on how they would fair under the new requirements

3

Implement new requirements

- Start at lower thresholds
- Increase the thresholds each trimester until requirements are in full effect



Keys Questions for Compliance

Are the data managers being notified of upcoming infusions soon enough?

- Address backlog of registrations – get caught up on at least 2814s so that you can use your CPI lists to plan work

Will your workflow support be completing critical forms by the due date?

- Critical Forms will need to be completed within 1-2 weeks of infusions
- Due dates for Long-Term Follow-Up Forms will be extended



Addition of Non-US Centers

Pilot Centers:

- Forms Requirement delayed due to COVID
- CTA Lists still requested

Introducing Reporting Levels for all Non-US Sites:

- NMDP Only (required if getting products from Be the Match)
- All Allos (required if participating in TCSA)
- All Allos + All Autos

Centers will be asked to commit to TED or CRF and a reporting level



Questions?

More to Come . . .
Keep an Eye Out for
CIBMTR CPI Update Memos

