

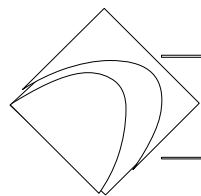
CPI

(Continuous Process Improvement)

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CIBMTR[®]

**CENTER FOR INTERNATIONAL BLOOD
& MARROW TRANSPLANT RESEARCH**

Objectives

- ◆ Knowledge of CPI program and purpose
- ◆ When to submit consent documents
- ◆ What are liaisons
- ◆ When will CPI apply
- ◆ What to do about backlog

National Marrow Donor Program (NMDP) Process

- ◆ CPI Phase I – search forms
- ◆ CPI Phase II – recipient forms
- ◆ CPI Phase III – research samples
- ◆ CPI Phase IV – donor forms

Health Resources and Services Administration (HRSA)

- ◆ Research (data collection) is mandated
- ◆ Transplant Center Specific Study
- ◆ Outcome Analyses

Stem Cell Therapeutics Outcomes Database (SCTOD)

- ◆ Data collection is required
- ◆ TED level data
 - ◆ Pre-TED
 - ◆ Post-TED
 - ◆ INF form

When Forms Are Past Due

Form 2000 & Pre-TED

- 60 days after infusion

Form 2100 & 100-day Post-TED

- 120 days after 100-day anniversary

Form 2200 & 6 months, 1 year, 2 years Post-TEDs

- 90 days after infusion anniversary

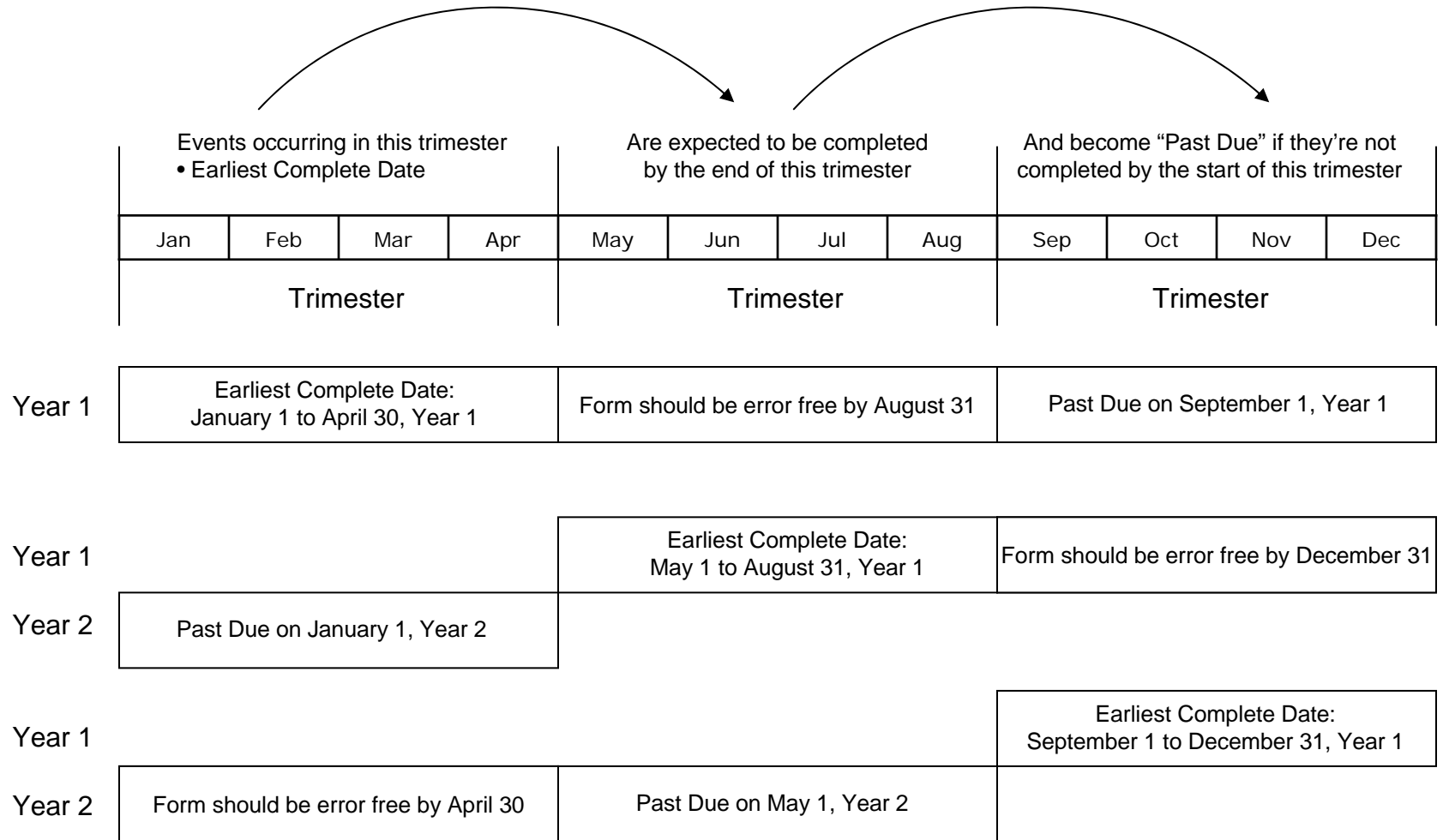
Form 2300 & 3–years and beyond Post-TEDs

- 45 days after infusion anniversary

CPI Phase II Requirements

- ◆ **90% of Forms (TED level and Research) must be completed by the end of the trimester after their *Earliest Complete Date***
 - ◆ **January**
ECD- May 1 through August 31
 - ◆ **May**
ECD- September 1 through December 31
 - ◆ **September**
ECD- January 1 through April 30

CPI Goal: 90% of Forms Completed for Each Trimester



CPI Phase II Requirements

(continued)

- ◆ **Forms must be error-free**
- ◆ **Inserts associated with the form must be error-free**

CPI Phase II Requirements

(continued)

- ◆ **Consent approval documents**
 - ◆ **Must be current**
 - ◆ **Must be on file with CIBMTR - Minneapolis**
- ◆ **Data Transmission Agreement (DTA)**

CPI Phase II Requirements

(continued)

- ◆ **Due Process**
 - ◆ **Good Standing**
 - ◆ **1st Warning**
 - ◆ **Probation Warning**
 - ◆ **Probation**
 - ◆ **Suspension**

CPI Due Process

Probationary Periods

- ◆ Good Standing – less than 90% of forms past due
- ◆ 1st Warning – 90% complete not met for 1 trimester
- ◆ Probation Warning – 90% complete not met for 2 consecutive trimesters
- ◆ Probation – 90% complete not met for 3 consecutive trimesters
- ◆ Suspension – more than 3 trimesters of non-compliance, access to NMDP donors may be restricted

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Year 1	Earliest Complete Date: January 1 to April 30, Year 1								Due by September 1, Year 1 1st Warning			
Year 2	Probation Warning				Probation				Suspension			

Liaisons

- ◆ Center assigned to a liaison
- ◆ Monitor/track CPI progress
- ◆ Answer questions
 - ◆ Clarify form questions
 - ◆ Clarify error reports
- ◆ Train center staff

CPI for Non-NMDP Infusions

- ◆ Trimester ending April 2008:
monitor only
- ◆ Trimester ending August 2008 at
70%
- ◆ Trimester ending December 2008 at
80%
- ◆ Trimester ending April 2009 at 90%

Voluntary CPI?

- ◆ **How can something that is voluntary have consequences?**
 - ◆ **Constraint not Consequence**
- ◆ **System that meets:**
 - ◆ **Your center's resource capabilities**
 - ◆ **CIBMTR's ability to produce quality studies**

Frustrated?



Existing Voluntary Model

- ◆ **In many cases - does not work**
 - ◆ Reactive
 - ◆ Overwhelming
 - ◆ Frustrating
- ◆ **There has to be a better way**



Fail to Plan – Plan to Fail

◆ Project Management Basics

- ◆ Specific due dates
 - ◆ Deliverables
 - ◆ Milestones
 - ◆ Deadlines
- ◆ Set Expectations - Meet or Exceed
- ◆ Communication – not only historical, negative
- ◆ Goals – long term vision
- ◆ Objectives – measurable steps to reach goal
- ◆ Constraints of scope, time, and resources

Project Management

- ◆ **But, I already have:**
 - ◆ Solid organizational & time management skills
 - ◆ I don't need to be a project manager also !!

- ◆ **Negotiate internally**
 - ◆ Scope of work – (externally too)
 - ◆ Deliverables – meet deadlines, priorities
 - ◆ Resources - # hours to complete each form

Project Management Benefits

- ◆ **Clear Feedback and Status**
 - ◆ Stakeholders and customers
 - ◆ Objective metrics

- ◆ **Provides direction**
 - ◆ Prioritize all others responsibilities
 - ◆ Sense of purpose and direction

Project Management Constraints

- ◆ **Scope – Deliverables**
 - ◆ Both included and NOT included
 - ◆ A project without scope constraints isn't a project; it's a disaster
- ◆ **Time – conflicting projects**
- ◆ **Resources**
 - ◆ People, technology & materials
 - ◆ Status quo - Don't plan to catch up

What is CIBMTR doing?

- ◆ **Quick Review of Project Management Steps**

CIBMTR G's and O's

- ◆ **Goal** — Produce high quality studies to advance the field of HCT

- ◆ **Objective** — Receive data that is:
 - ◆ Complete
 - ◆ Timely
 - ◆ Accurate
 - ◆ Representative of overall HCT community

CIBMTR Objectives

- ◆ **All requested forms are needed to maintain the epidemiologic integrity of the database**
- ◆ **Timely receipt of research forms is important to evaluate new trends in HCT**

CIBMTR Objectives

- ◆ **Incomplete and delinquent forms lead to prolonged postponement of planned analyses**
- ◆ **Long-term follow-up is needed**
 - ◆ **HCT outcomes are not biased by under-reporting of events**
 - ◆ **Foster the Late Effects W/C & QOL**

Scope – to meet objectives

- ◆ **CPI Constraint – metric that will help both of us**
 - ◆ **Setting expectations**
 - ◆ **Time/Resource constraint resolution**
 - ◆ **EVERY organization has resource allocation issues**

- ◆ **Customer Focus**
 - ◆ **CRC Liaisons assigned to each center**
 - ◆ **Build rapport to frequently review**
 - ◆ **Status**
 - ◆ **Issues**

Scope continued

- ◆ Focus on future
 - ◆ Plan and prioritize to get caught up and maintain that status
 - ◆ Study related materials
 - ◆ CTN related materials
 - ◆ Follow-up on patients
- ◆ CIBMTR work with your center
 - ◆ How can we help you?
 - ◆ Backlog
 - ◆ Estimate # hours/per form

Estimate # hours/form

- ◆ **Systems to collect data:**
 - ◆ Data comes from a good EMR or all paper?
 - ◆ Hybrid?
 - ◆ Data from Institutional database – DB type?
- ◆ **Time components & processes, in hours:**
 - ◆ “Translate” from your DB to our forms
 - ◆ Collect the medical records
 - ◆ Fill in the data on paper or on-screen
 - ◆ Contact patient or Follow-up doctor
- ◆ **Responsibilities other than CIBMTR data**
- ◆ **Many more categories - center dependant**
 - ◆ Efficient to gather data by section of form?

Scope continued

- ◆ **More than 'training'**
 - ◆ Learn from you
 - ◆ Ease of communication among
 - ◆ Your coworkers
 - ◆ Your customers

- ◆ **Tools**
 - ◆ FormsNet
 - ◆ AGNIS
 - ◆ Harmonized forms

Who can help?

- ◆ **See myself of Sharon Meiers**
- ◆ **Attend CPI roundtable this afternoon**
- ◆ **Attend Christine Lange's presentation tomorrow**
 - ◆ **CPI – How To's**

Thank *You!*

- ◆ **We sincerely appreciate your commitment to the CIBMTR**
- ◆ **The ability to meet the research agenda of the CIBMTR, an agenda determined by you and others in the HCT community, depends on the willingness of our participating centers to provide data as requested**