



Balance®: Drafting an RTSM Team and Training for Go-Live

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Sr. Project Manager

PROMETRIKA: Who We Are

- Full-service CRO located in Cambridge, MA
- Medidata Gold Services Partner

What kind of Sponsor are you?

Perfect World

- Unlimited resources!
- Long timeline!
- Can dedicate as many team members as necessary!



Reality

- Fixed resources
 - Balance is an investment.
- Need to go to market ASAP
 - Single compound
 - Limited pipeline
- Team members are cross-functional

Balance Roles – 22 Different Ones!

ROLE	OID	SCOPE	RESTRICT SITES	CAN CHANGE SUBJECT ARM	CAN CONFIRM SHIPMENT RECEIVED	CAN CONFIRM SHIPMENT SENT	CAN CREATE QUARANTINE	CAN DESIGN STUDY	CAN DISOLVE SHIPMENT	CAN EDIT CAPS	CAN EDIT LIVE STUDY	CAN MANAGE DEPOT	CAN MANAGE INVENTORY ALERTS	CAN MANAGE INVENTORY ITEMS	CAN MANAGE LOTS	CAN MANAGE PACKLISTS	CAN MANAGE QUARANTINE	CAN MANAGE RAND BLOCK LIST	CAN MANAGE SITE	CAN MANAGE STUDY	CAN MANAGE SUBJECT	CAN MANUALLY CREATE PLAN	CAN MANUALLY CREATE SHIPMENT	CAN REMOVE SUBJECT FROM RANDOMIZA	CAN REPORT PHYSICAL INVENTORY	CAN SEE SHIPMENT EMAIL	CAN SEE BLINDED DATA	CAN UNBLIND INVENTORY ITEM	CAN UNBLIND SUBJECT	CAN VIEW AUDITS	CAN VIEW LOGISTICS	NOTIFICATION SUPPLY PLAN	NOTIFICATION FORCED ALI					
ASSISTANT PROJECT MANAGER (BLINDED)	STUDY-APM-BL	STUDY	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO				
BIOSTATISTICIAN (BLINDED)	STUDY-BIO-BL	STUDY	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO			
BIOSTATISTICIAN (UNBLINDED)	STUDY-BIO-UN	STUDY	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO			
CLINICAL RESEARCH ASSOCIATE (BLINDED)	SITE-CRA-BL	STUDY	YES	NO	YES	YES	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO		
CLINICAL RESEARCH COORDINATOR (BLINDED / CAN REPORT PHYSICAL INVENTORY)	SITE-CRC-BLPI	SITE	NO	NO	YES	YES	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO		
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SAFETY MONITOR (BLINDED, CAN UNBLIND)	STUDY-SAF-CU	STUDY	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	
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SHIPPER MANAGER (BLINDED)	SHIP-MAN-BL	DEPOT	NO	NO	YES	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	
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SUPPLY MANAGER (BLINDED)	STUDY-SPM-BL	STUDY	NO	NO	YES	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	
SUPPLY MANAGER (UNBLINDED)	STUDY-SPM-UN	STUDY	NO	NO	YES	YES	YES	NO	YES	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	NO	
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Balance Team Draft Rules

1. Not all roles need to be assigned
2. Roles have overlapping responsibilities

Balance Roles

ROLE	OID	SCOPE	RESTRICT SITES	CAN CHANGE SUBJECT ARM	CAN CONFIRM SHIPMENT RECEIVED	CAN CONFIRM SHIPMENT SENT	CAN CREATE QUARANTINE	CAN DESIGN STUDY	CAN DISOLVE SHIPMENT	CAN EDIT CAPS	CAN EDIT LIVE STUDY	CAN MANAGE DEPOT	CAN MANAGE INVENTORY ALERTS	CAN MANAGE INVENTORY ITEMS	CAN MANAGE INVENTORY LOTS	CAN MANAGE PACKLISTS	CAN MANAGE QUARANTINE	CAN MANAGE RAND BLOCK LIST	CAN MANAGE SITE	CAN MANAGE STUDY	CAN MANAGE SUBJECT	CAN MANAGE SUPPLY PLAN	CAN MANUALLY CREATE SHIPMENT	CAN MARK SHIPMENT	CAN REMOVE SUBJECT FROM RANDOMIZA	CAN REPORT PHYSICAL INVENTORY	CAN SEE SHIPMENT EMAIL	CAN SEE BLINDED DATA	CAN UNBLIND INVENTORY	CAN UNBLIND INVENTORY ITEM	CAN VIEW SUBJECT	CAN VIEW AUDITS	CAN VIEW LOGISTICS	NOTIFICATION SUPPLY PLAN	NOTIFICATION FORCED ALI			
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Balance Team Draft Rules

1. Not all roles need to be assigned
2. Roles have overlapping responsibilities
3. Roles are not customizable

Balance Roles

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SYSTEM ADMINISTRATOR (UNBLINDED, CAN UNBLIND)	STUDY-SA	STUDY	NO	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

Balance Team Draft Rules

1. Not all roles need to be assigned
2. Roles have overlapping responsibilities
3. Roles are not customizable
4. Each account can only be assigned 1 Balance role (at a time)
 - But each role can be assigned to multiple accounts...
5. Switching roles in the live environment is not recommended

Scouting Strategies

Strategy #1: Assess Your Talent Pool

- How many team members are assigned to this project?
- What is the team composition and where are they coming from?
- Can more team members be assigned if necessary?
- How many Balance roles can be assigned given the number and kinds of team members you have?

Strategy #2: Assess Your Positions

- Which responsibilities do I need covered?
- What's the fewest number of roles I can get away with?
- Do I have enough team members → to fill enough roles → to cover all the necessary responsibilities?

Strategy #3: The Blind Side

Should the key players on your Balance team be blinded?

- 2 Key Roles:
 - Study Manager (Unblinded)
 - Supply Manager (Unblinded)
- If you are working with multiple vendors to implement Balance, who gets your unblinded players

Blinded Roles: Fun Fact



Role	OID	Scope	can see blinded data
Assistant Project Manager (blinded)	STUDY-APM-BL	study	no
Biostatistician (blinded)	STUDY-BIO-BL	study	no
Biostatistician (unblinded)	STUDY-BIO-UN	study	yes
Clinical Research Associate (blinded)	SITE-CRA-BL	study	no
Clinical Research Coordinator (blinded/ can report physical inventory)	SITE-CRC-BLPI	site	no
Clinical Research Coordinator (blinded)	SITE-CRC-BL	site	no
Pharmacist (blinded)	SITE-PH-CU	site	no
Pharmacist (unblinded)	SITE-PH-UN	site	yes
Primary Investigator (blinded)	SITE-PI-BL	site	no
Primary Investigator (blinded,can unblind)	SITE-PI-CU	site	no
Project Manager (blinded)	STUDY-PM-BL	study	no
Project Manager (blinded,can unblind)	STUDY-PM-UN	study	no
Safety Monitor (Blinded, Can Unblind)	STUDY-SAF-CU	study	no
Safety Monitor (unblinded)	STUDY-SAF-UN	study	yes
Shipper Manager (blinded)	SHIP-MAN-BL	depot	no
Shipper Manager (unblinded)	SHIP-MAN-UN	depot	yes
Study Manager (blinded)	STUDY-SM-BL	study	no
Study Manager (blinded,can unblind)	STUDY-SM-CU	study	no
Study Manager (unblinded)	STUDY-SM-UN	study	yes
Supply Manager (blinded)	STUDY-SPM-BL	study	no
Supply Manager (unblinded)	STUDY-SPM-UN	study	yes
System Administrator (unblinded, can unblind)	STUDY-SA	study	yes

Training Camp



Balance Training Plan

- Balance Workshop
 - Need relevant attendees
- **UAT**
 - You are all on the hook! Every assigned role should participate in UAT
 - Train while performing UAT to shorten timeline
- Cross-training
 - Remember, each person can only occupy 1 role at a time
 - Train in different roles in the UAT environment
 - Only switch roles if absolutely necessary in the live environment

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