

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

Kathy Zheng, MPH 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 crossfunctional



#### **Balance Roles – 22 Different Ones!**

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#### **Balance Team Draft Rules**

1. Not all roles need to be assigned

2. Roles have overlapping responsibilities



#### **Balance Roles**

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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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#### **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  $\rightarrow$  to fill enough roles  $\rightarrow$  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
- <u>UAT</u>
  - 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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