



TIMI Operations

Polly Fish, *Director of Operations*



An Academic Research Organization of
Brigham and Women's Hospital and Harvard Medical School



TIMI Study Group Offices



Longwood Medical Area, Boston, Massachusetts



Harvard Medical School

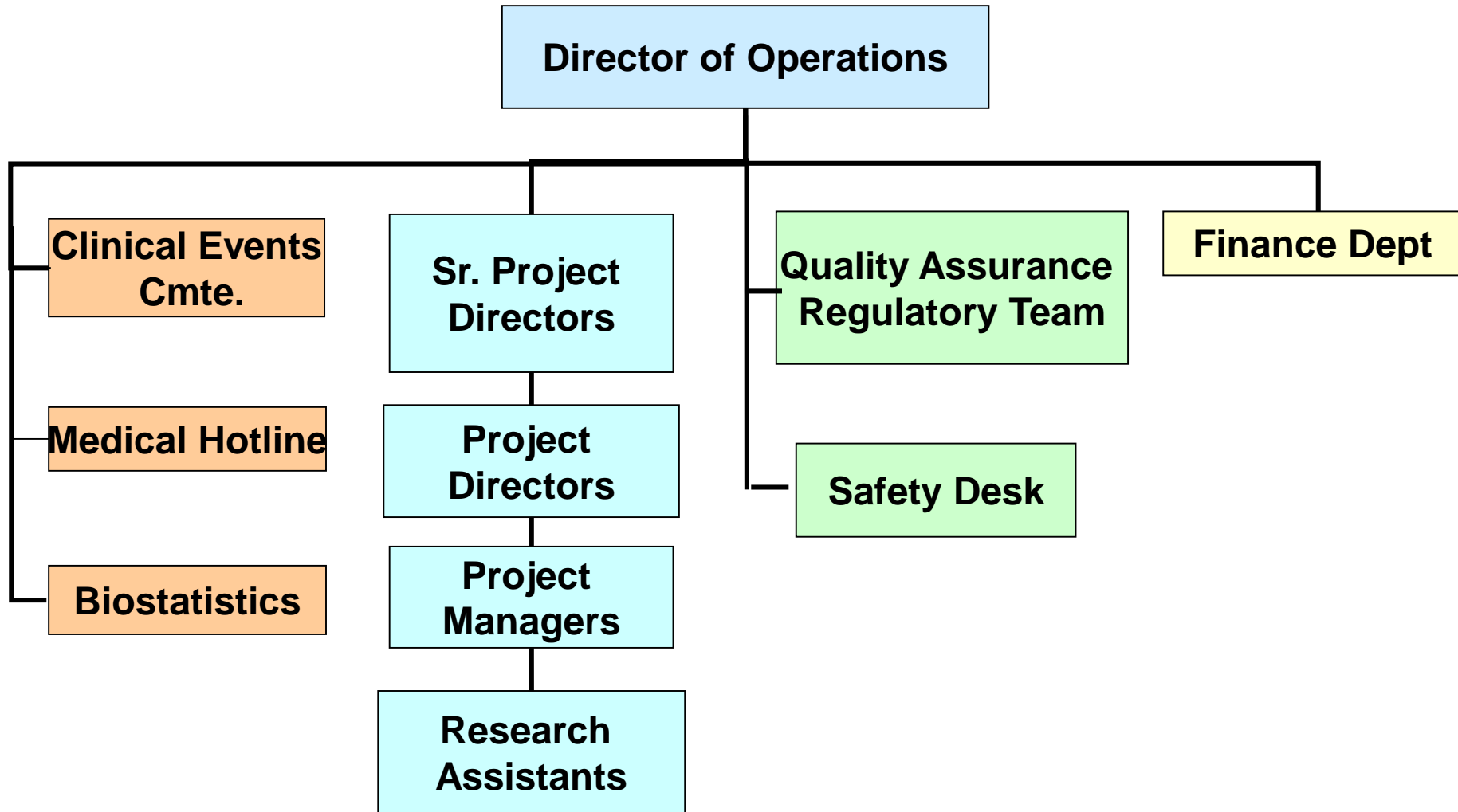
Confidential



Brigham and Women's Hospital



Operational Organization





TIMI Trial Operations Team

- **Director of Operations**
 - Provides oversight; strategic planning
- **Senior Project Director/Project Director**
 - Leads trial operations team
 - Works hand-in-hand with TIMI Trial PI, Co-PI
 - Interacts w/ Sponsor & Vendors
- **Project Manager**
 - Oversee daily management
 - Supervise RAs
- **Research Assistants (5-10)**



Global Investigator Network

6 Continents, 52 Countries
8000+ Investigators

**North
America**

Europe

Asia

Japan

Africa

**South
America**

**Australia
New Zealand**





Site Selection & Startup

✓ Identify Countries

- Select most productive countries based on relevant prior trial metrics
- Use TIMI Database & Sponsor Database
- National Lead Investigators experience

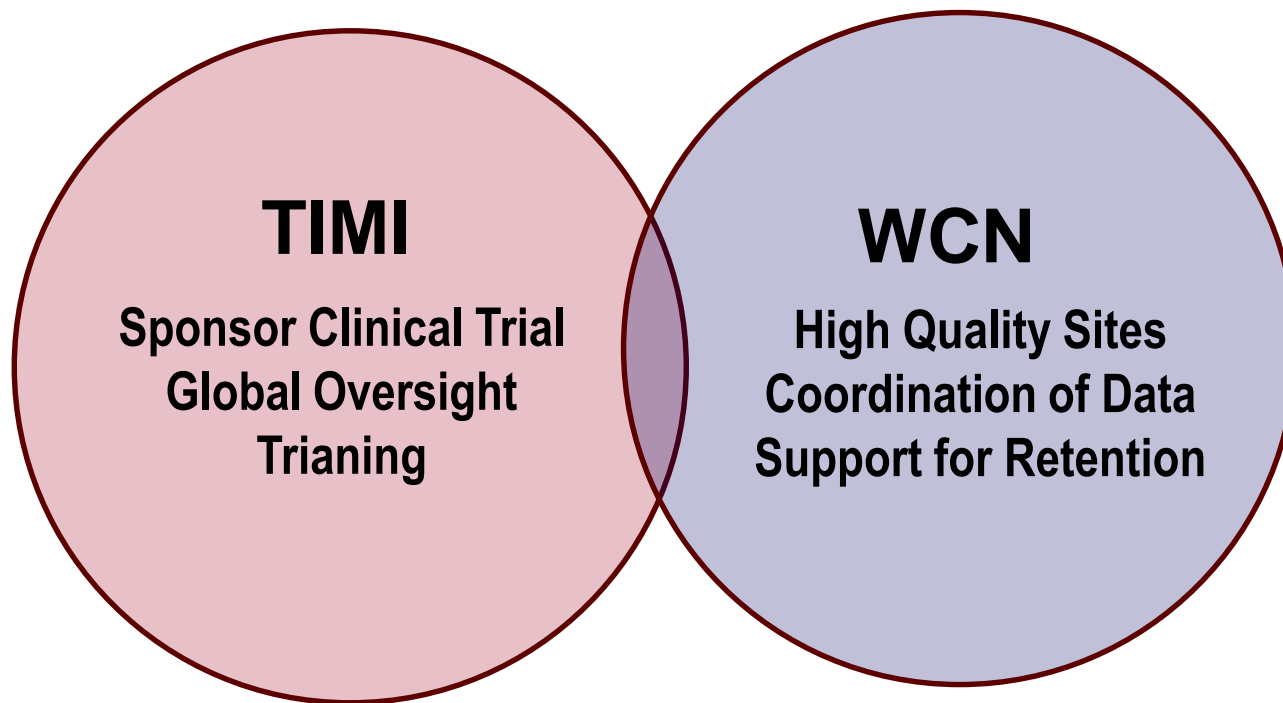
✓ High Quality, Appropriate Sites

- Sufficient patient population
- Rapid Regulatory/Ethics Approval
- Excellent enrollment, retention, & data metrics



TIMI - WCN Collaboration

Each party brings unique skills to achieve common goal



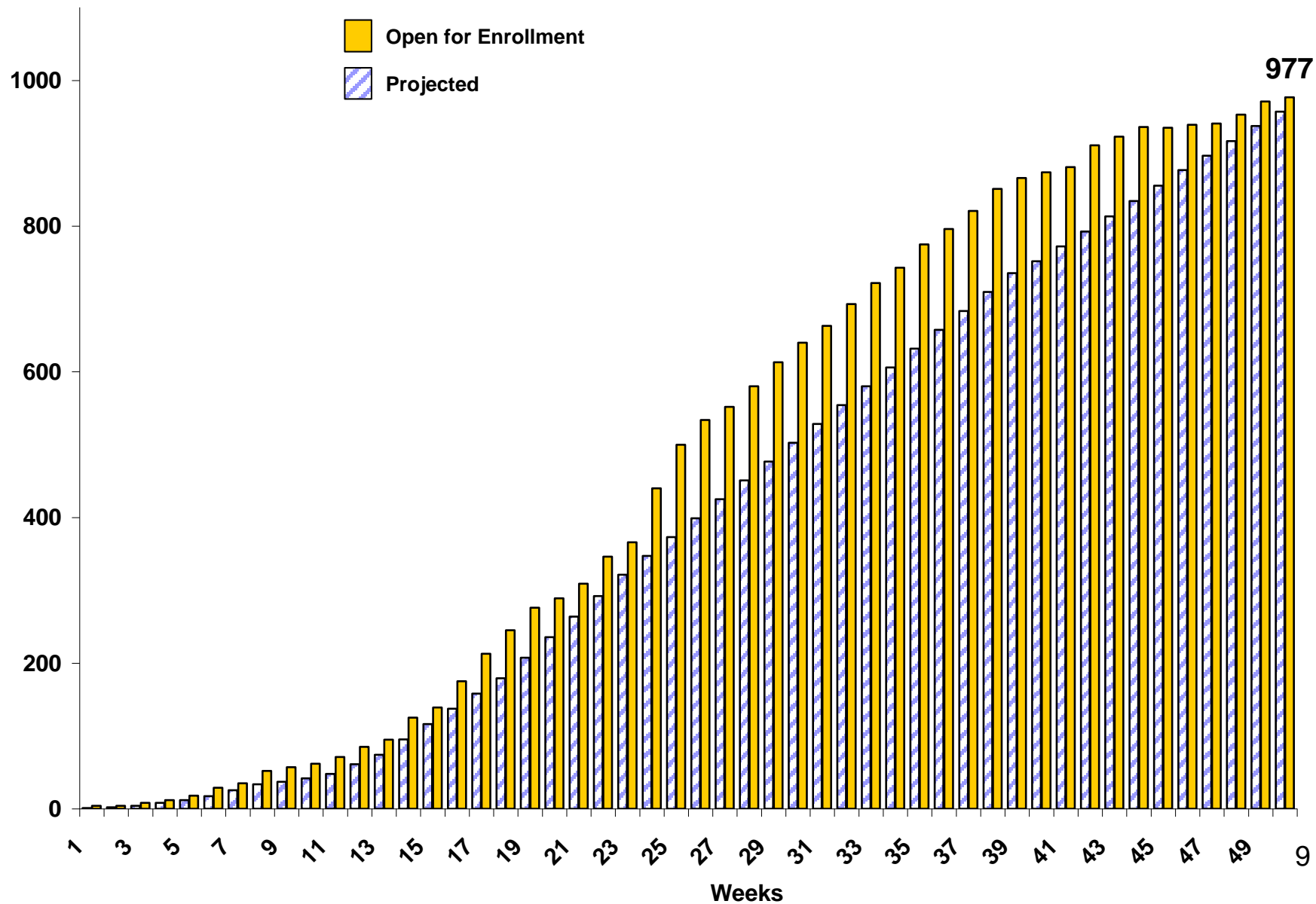


WCN Collaboration

- **Network of qualified, experienced PIs & SCs committed to recruitment targets & providing quality data in a timely manner**
 - Careful selection
 - PIs known to NLI and committed to research
- **Rapid activation & enrollment**
 - Typically approved w/in 6 mos of protocol availability
 - 95% of sites activated & enrolling subjects
 - Able to identify stable patients in advance to allow for rapid start-up



Global Site Start-up





WCN Site Support

Active during the trial:

- **Track Country & Site Performance**
 - Informed on individual site progress
 - Country issues identified-reported
- **Support recruitment at high enrolling sites and enhance performance of moderate & low enrolling sites**
- **Committed to Retention**
 - Educate Sites: Involve both PI & SC
 - Educate subjects: expectations for follow-up visit schedules and information on study drug





WCN: Site support

- **Training**

Interactive regional mtgs

- **Communication**

Regular teleconferences

NLI attendance at Steering Committee Meetings

- Aware of each sites performance
- Has contact with individual site PIs regularly

Learn from questions what is unclear/problematic

Ensures site retraining or clarification as needed



#2

NETHERLANDS

NLI: DR. TON OUDE OPHUIS



No. Subjects – 1907 No. Sites - 36
Average subjects per site = 53
Subject Retention 99.4%

Top Performing Country

NETHERLANDS

NLI: DR. TON OUDE OPHUIS



No. Patients – 1560 No. Sites - 41
Average subjects per site = 38
Subject Retention 99.94%



TIMI – WCN Collaboration

Supports the completion of high-quality clinical trials that answer important scientific questions and potentially shape clinical practice

