CLINIPACE WORLDWIDE

One-Stop Shopping for Clinical Trial Management:

The Value Proposition of a dCRO

Introduction

PRESENTERS

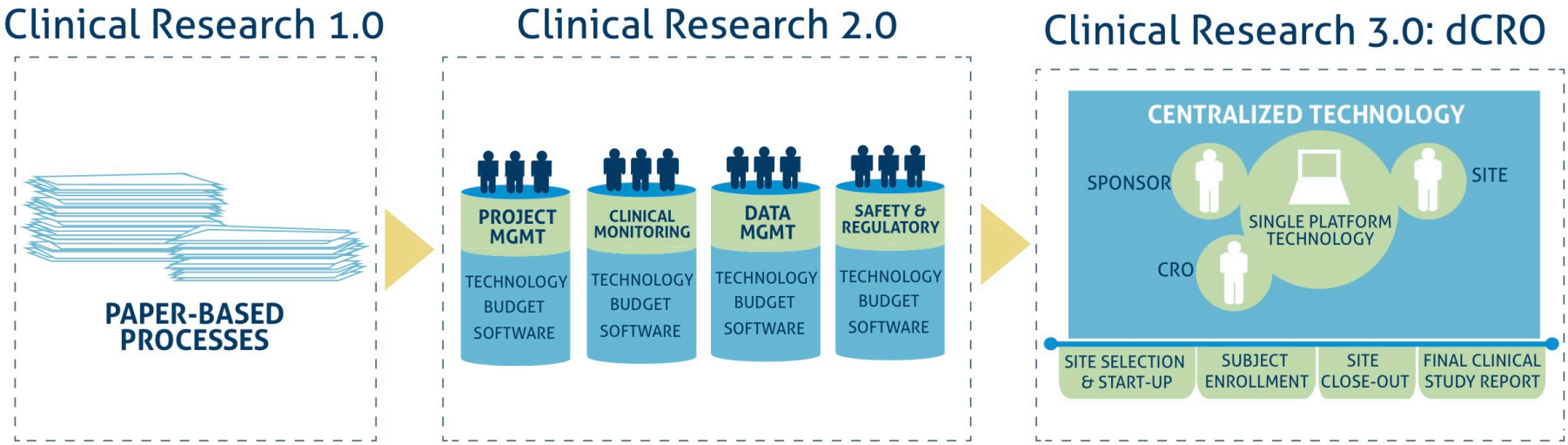
Cynthia Venendaal, CCRA, MPH, PhD
Director, Global Project Operations
Clinipace Worldwide

Crista Casey BS, BA, CCRA
Global Project Director,
Clinipace Worldwide

MODERATOR

Chris Porter
President and General Counsel,
Clinipace Worldwide

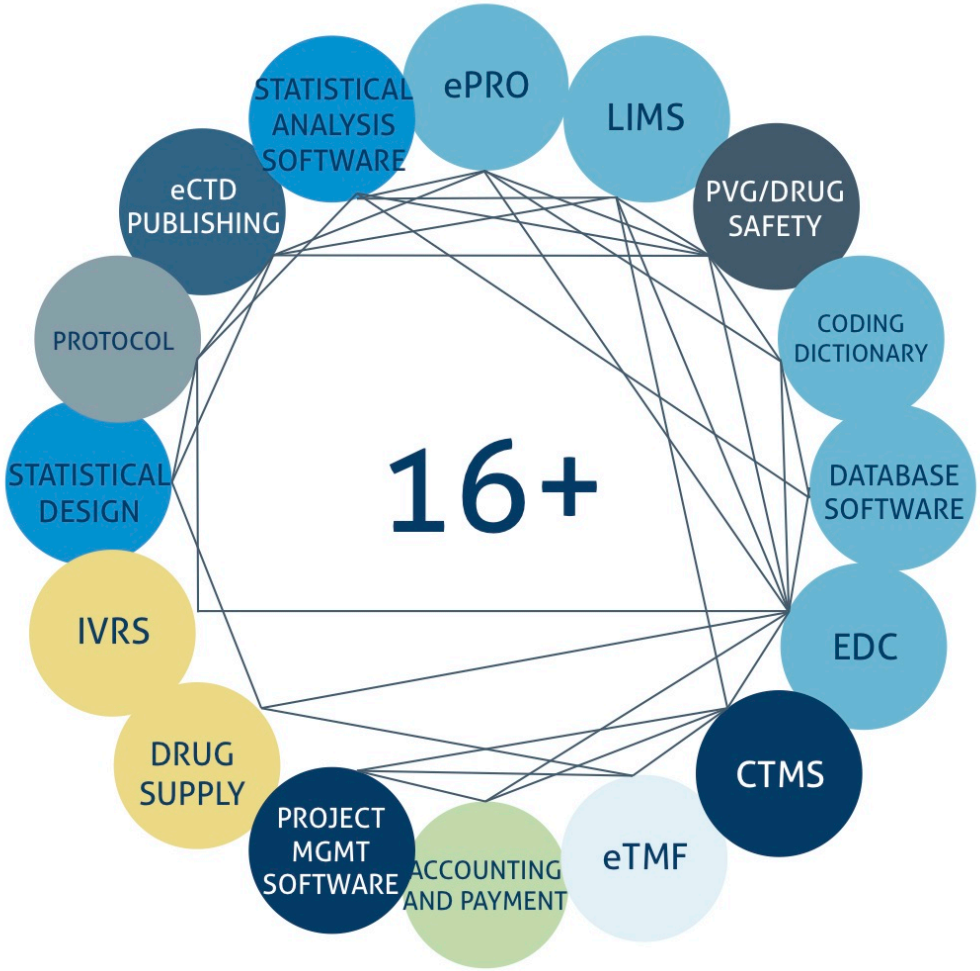
Rise of the dCRO



CLINIPACE WORLDWIDE

Polling Question #1

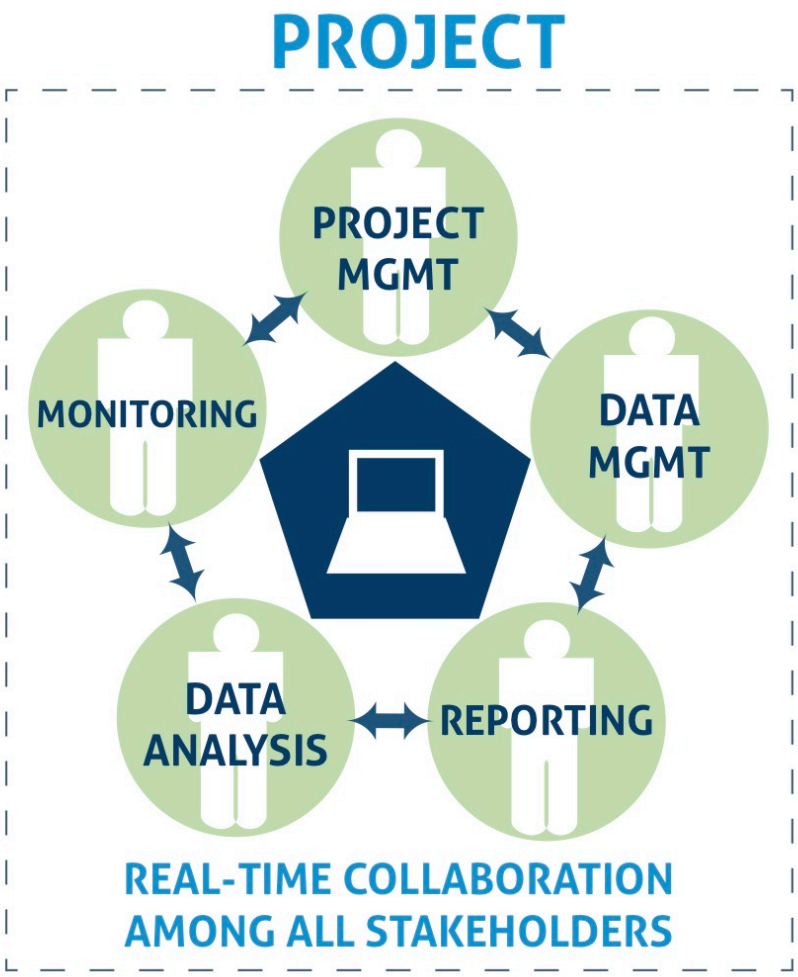
Avg. # of Databases in a Traditional CRO



Technology = Backbone, People = Heart

- ✓ The heart of the transformation?
  - People share vision of technology as a tool that brings:
    - Efficiency to processes
    - Quality to outcomes
    - Decreased costs
  - Technology is the backbone of successful processes, not an add-on
  - The dCRO model optimizes tailored resources so just the right number of individuals are engaged
    - Vs “selling” people by the hour
    - Vs each stakeholder adding his/her specialized technology

Transforming Project Teams



BENEFITS:

- Methods, data, metadata are transparent to all stakeholders
- Processes more efficient
- Rigid definitions of departments within project teams aren't required
- Integrated communication; walls separating functions in traditional CROs broken down

Transforming Individual Roles

- ✓ Shift from logistics and processes > strategy and issues
  - Trouble-shooting
  - Streamlining
  - Decision-making
  - Resource management
  - Study site coaches vs clerks/auditors
- ✓ Real-time data queries > site addresses any issues > resolve immediately
- ✓ Site visits, CRA deployment more effective/strategic

Benefits of a dCRO

Intro to TEMPO 4.0

- ✓ One-stop shopping for clinical trial management
- ✓ Integrated, cloud-based platform
- ✓ Single interface
- ✓ Real-time access to all study data (role-based permissions)
- ✓ Configurable modules:
  - Study Portal
  - Trial Manager
  - eClinical
  - Monitoring and Trip Reports
  - Safety Management & Reporting
  - eTMF

Role-Specific Benefits of TEMPO 4.0

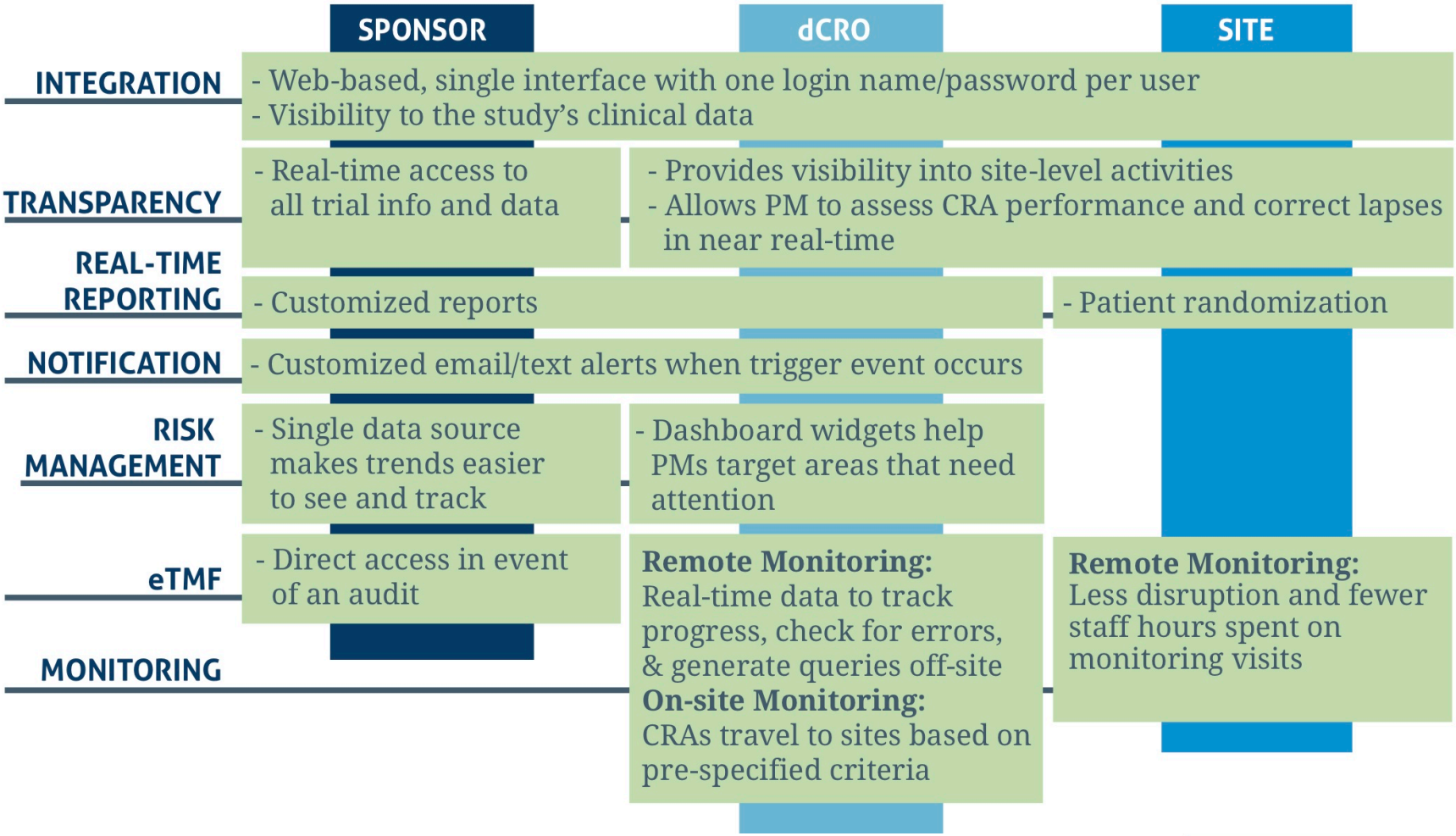
STUDY STAGE: **START-UP**

	SPONSOR	dCRO	SITE
INTEGRATION	- Web-based, single interface with one login name/password per user - Visibility to the study's clinical data		
TRANSPARENCY	- Real-time access to all trial info and data	All study documents on single platform - Reduces back & forth between CRO & site - No paper documents	
REAL-TIME REPORTING	- Up-to-date, customizable reports	- Eliminates need to update status reports - Easy-to-access info	- Real-time patient randomization
eTMF	- Direct, real-time access in the event of an audit	- Single document repository makes it easier to keep TMF up-to-date	

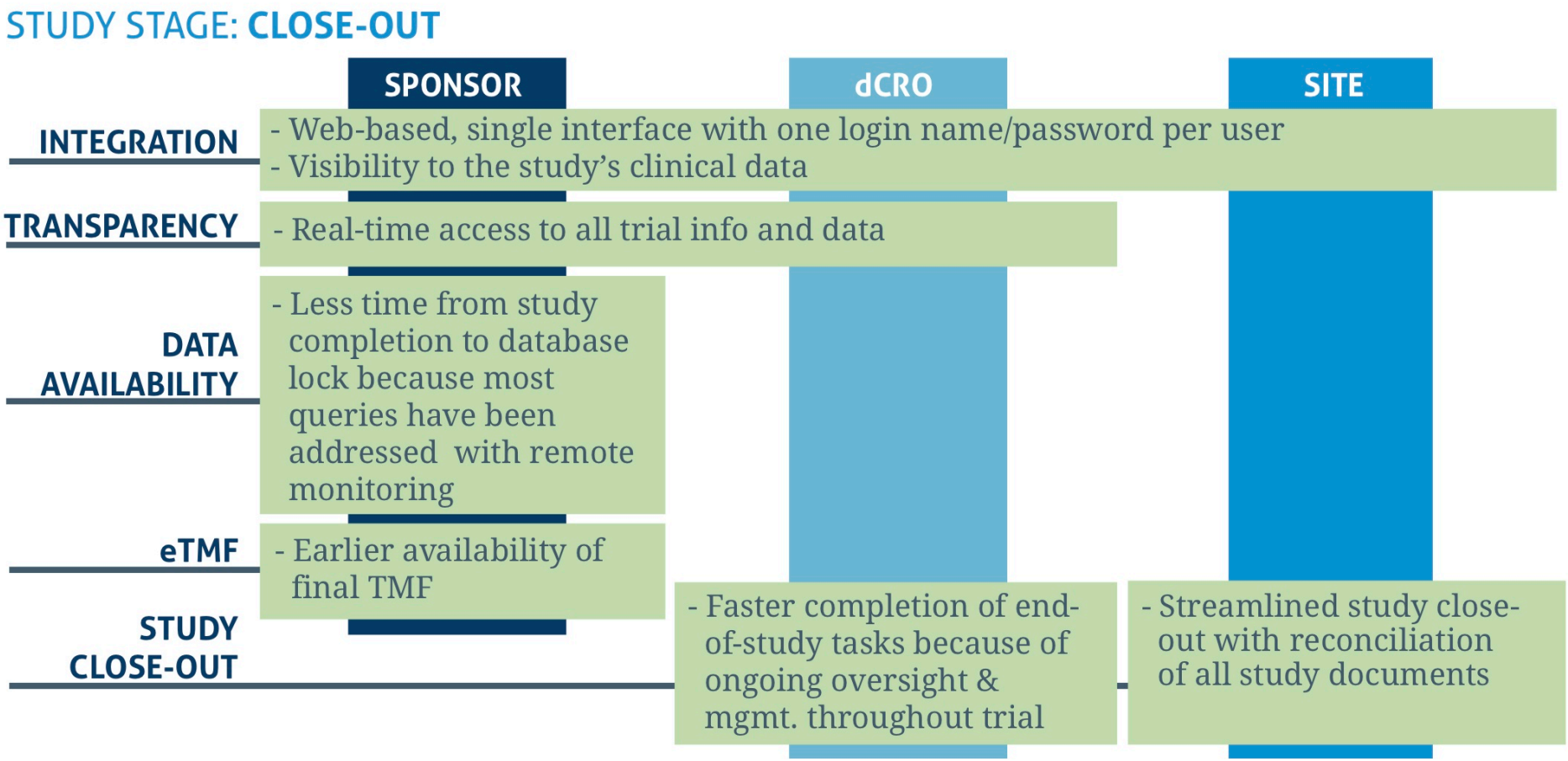
CLINIPACE WORLDWIDE

Role-Specific Benefits of TEMPO 4.0

STUDY STAGE: ENROLLMENT



Role-Specific Benefits of TEMPO 4.0



CLINIPACE WORLDWIDE

Polling Question #2

CLINIPACE WORLDWIDE

Questions?