

BUILDING YOUR CENTRAL MONITORING TEAM: PLAYERS, SKILLS, STRUCTURE & COMMUNICATION

Christina Dinger

Associate Director, Central Monitoring; PRA Health Sciences

Lynn Demings

Senior Manager, Central Monitoring; PRA Health Sciences

PRESENTATION OVERVIEW

- ▶ Drivers of Central Monitoring
 - ▶ Central Monitoring – Where does it fit?
 - ▶ Historical Face of Clinical Trials
 - ▶ Preparing for the Future – Reshaping the Organization & Its People
 - ▶ Setting a New Organizational Framework
 - ▶ Leveraging BIG data & Supporting Central Monitoring
 - ▶ Unifying Central Monitoring
 - ▶ Integrating & Cross-Pollinating Roles
 - ▶ Key Considerations – Take a ways
 - ▶ Questions
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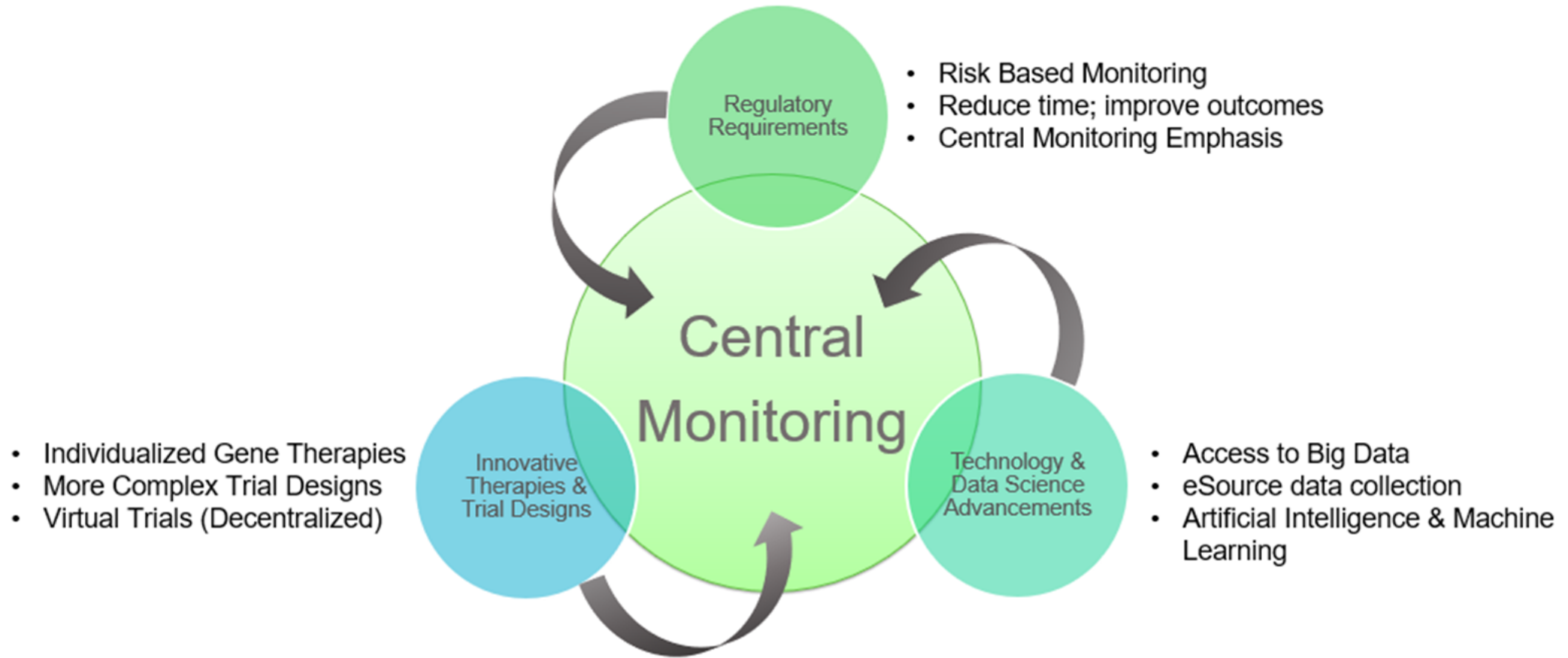
REGULATORY GUIDANCE

The EMA guidance document (2013), recommends implementing central monitoring and describes it as:

Document review, data review, and analysis performed remotely from the investigator site by the sponsor to examine the data collected in order to check compliance, identify unusual data patterns, deviations from protocol or missing or invalid data.

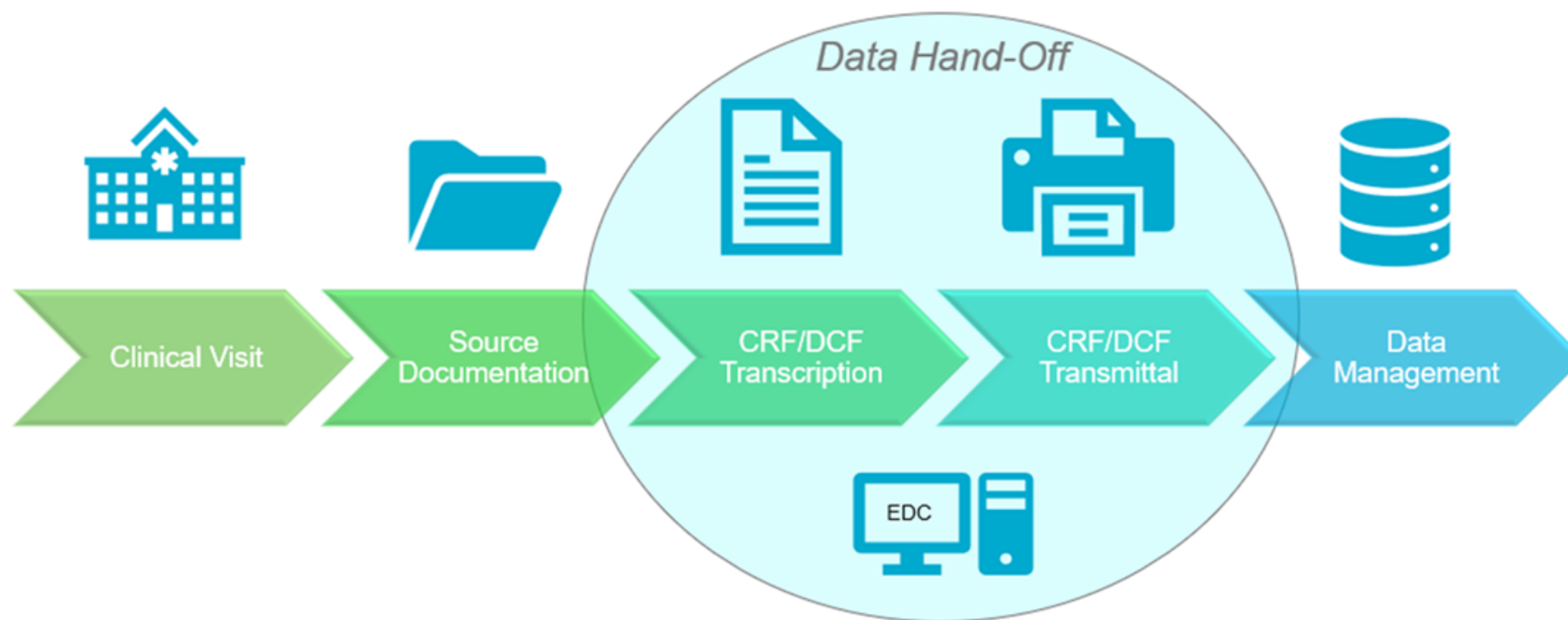
Examples of central monitoring techniques include *checks of submitted documents* (e.g. checklists for TMF content completed by investigators, training evidence etc.), *clinical data checks* (e.g. range checks, calendar checks etc., rate of reporting adverse events), *compliance data/metrics checks* (e.g. number of reported deviations from the protocol, rate of reporting adverse events... etc.).(P. 3)¹

CENTRAL MONITORING DRIVERS



CENTRAL MONITORING WHERE DOES IT FIT?

- ▶ Organizations still structured to support Paper data flow
- ▶ Clear Hand-off from Clinical Operations to Data Management
- ▶ Does not support decentralized trials and eSource data collection





Each year more clinical data is captured directly from study participants through eSource devices. Several companies surveyed during a 2018 SCDM forum stated that over 70% of clinical data volume is **not** coming from EDC.¹



Integration of Electronic Health Records (EHR) directly to EDC systems or cloud-based solutions eliminates transcription from source documents and Source Document Verification (SDV).²



Decentralized (i.e. virtual) study designs are being deployed to support patient centricity and to make study participation more assessible by collecting data virtually -- outside the traditional clinical setting.³

¹ NADOLNY, ZAMBAS, TORCHE, BHARDWAJ (2019). THE EVOLUTION OF CLINICAL DATA MANAGEMENT TO CLINICAL TO DATA SCIENCE. SOCIETY FOR CLINICAL DATA MANAGEMENT [HTTPS://SCDM.ORG/6588/](https://scdm.org/6588/)

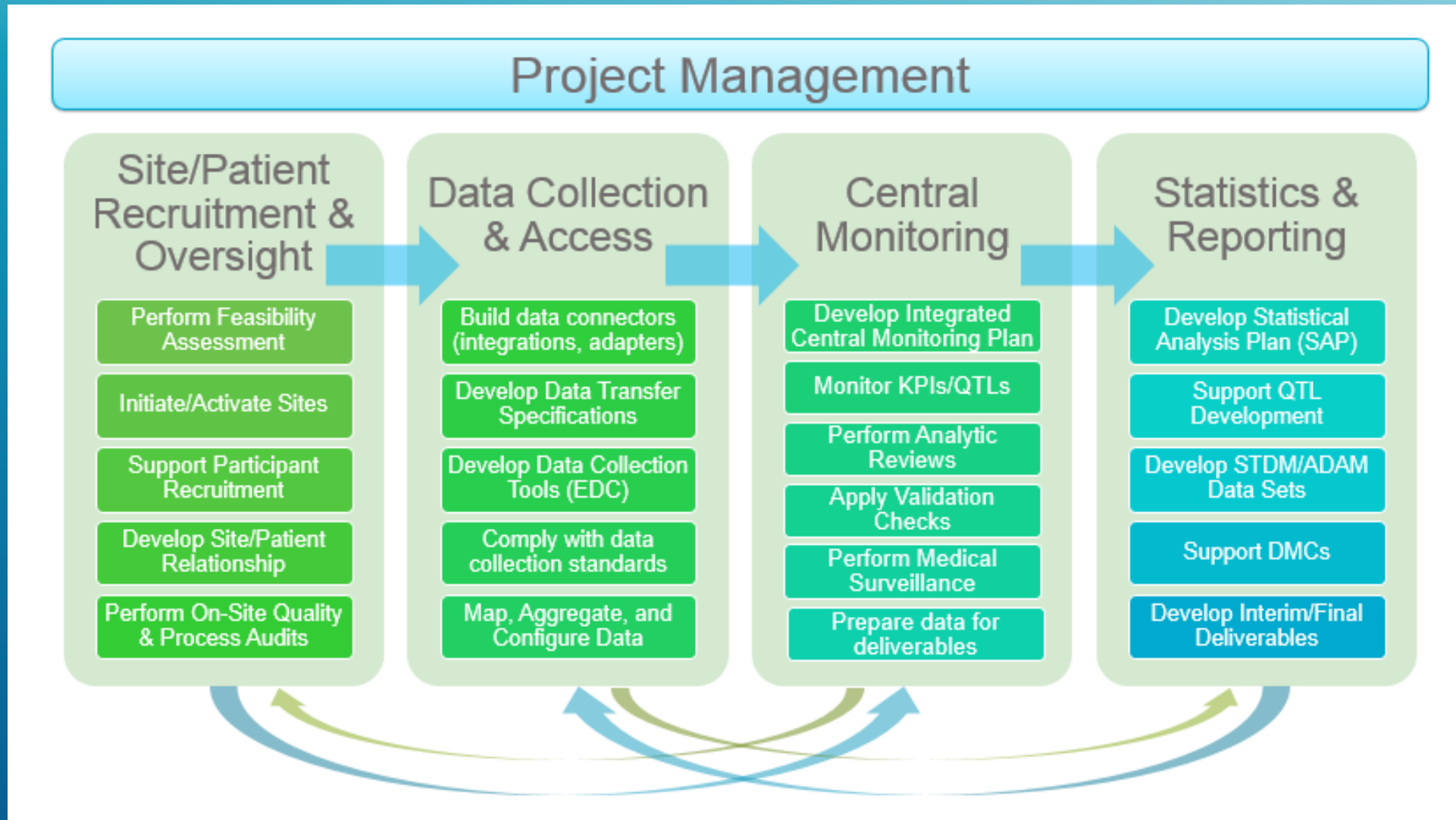
² ROCCA, ASARE, ESSERMAN, DUBMAN, GORDON (2019). SOURCE DATA CAPTURE FROM EHRS: USING STANDARDIZED CLINICAL RESEARCH DATA. FEDERAL DRUG ADMINISTRATION [HTTPS://WWW.FDA.GOV/MEDIA/132130/DOWNLOAD](https://www.fda.gov/media/132130/download)

³ MEDIDATA (2019). VIRTUALIZING CLINICAL TRIALS. [HTTPS://WWW.MEDIDATA.COM/WP-CONTENT/UPLOADS/2019/05/VIRTUALIZING-CLINICAL-TRIALS_MEDIDATA_WHITE-PAPER-MAY-19.PDF](https://www.medidata.com/wp-content/uploads/2019/05/virtualizing-clinical-trials_medidata_white-paper-may-19.pdf)

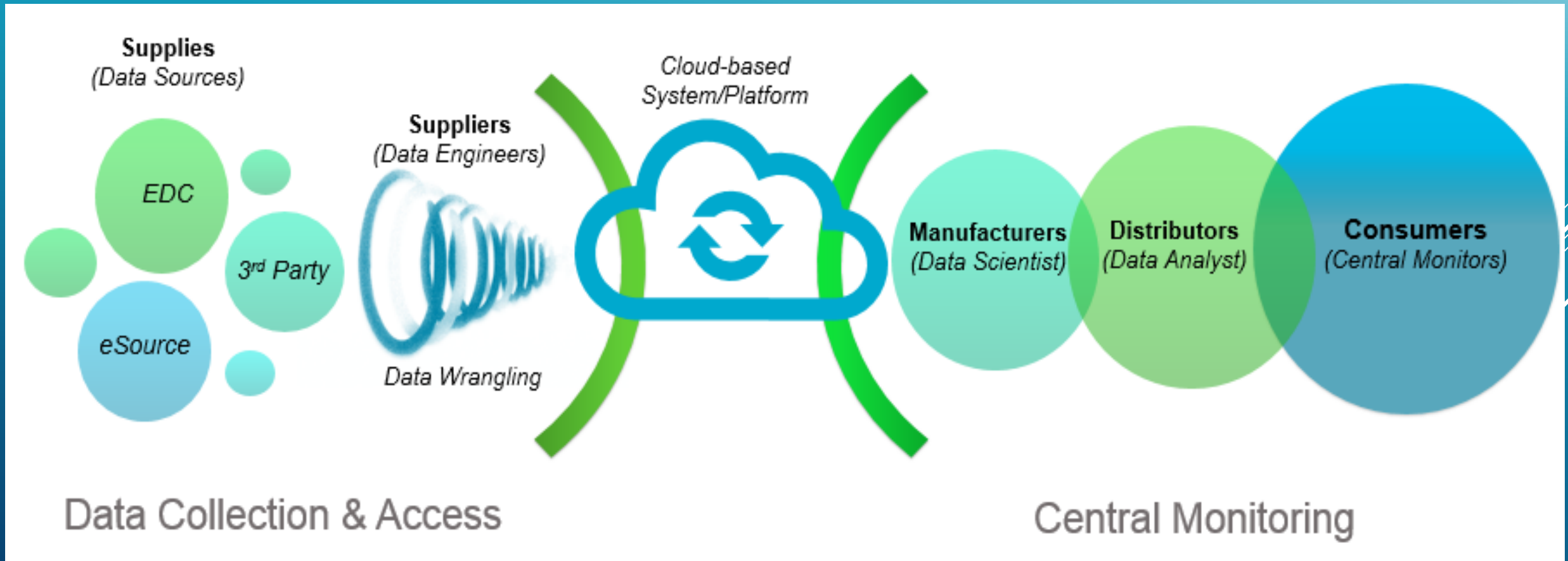
PREPARING FOR THE FUTURE – RESHAPING THE ORGANIZATION & ITS PEOPLE

- ▶ Create an organizational framework to harness *Big Data* and support Central Monitoring
- ▶ Embed Data Science into Central Monitoring to empower Central Monitors
- ▶ Remove department silos to develop a unified Central Monitoring business unit
- ▶ Integrate and cross-pollinate roles to promote collaboration & efficiency

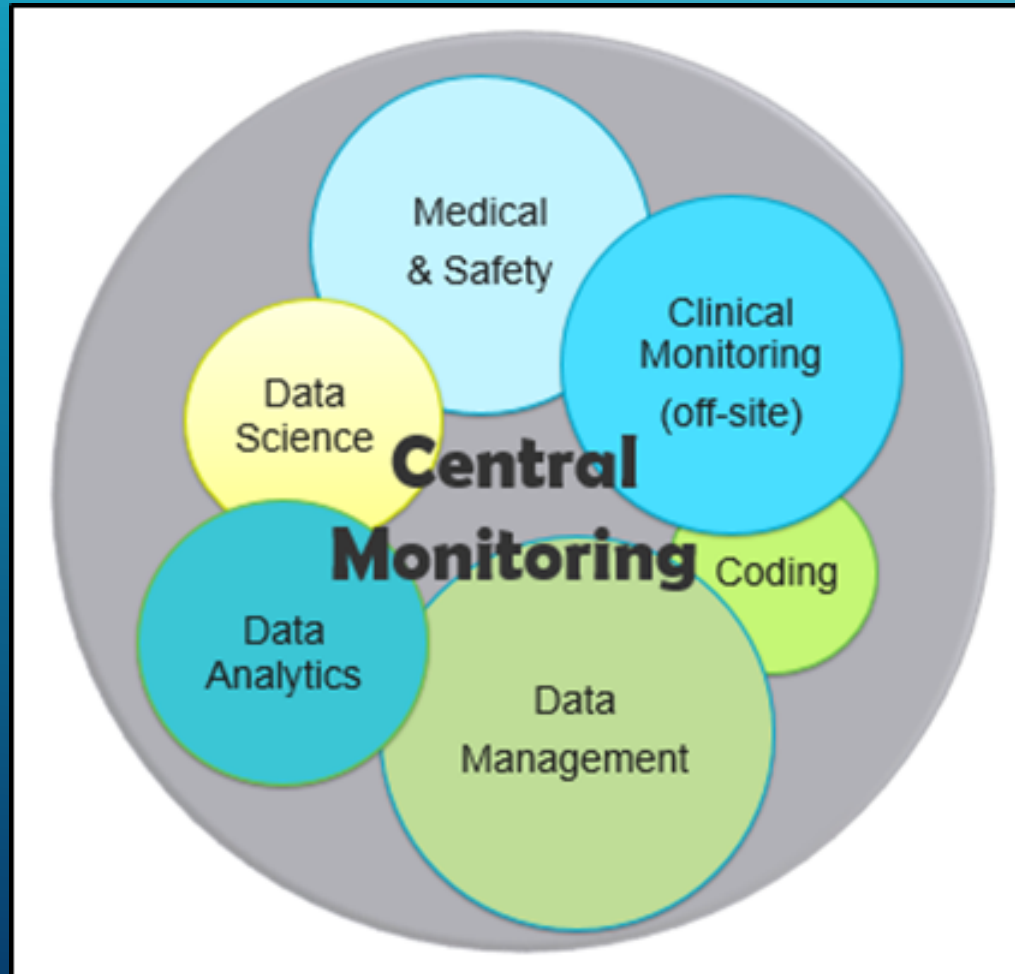
CREATE AN ORGANIZATION FRAMEWORK



LEVERAGING BIG DATA & SUPPORTING CENTRAL MONITORING



UNIFY CENTRAL MONITORING – MORE THAN JUST A PAPER EXERCISE



Conglomerate of Silos

- ✓ Align Central Monitoring roles in a single business unit
- ✓ Remove departmental silos/barriers
- ✓ Reduce reporting lines (flatten org chart)
- ✓ Leverage technology to support an E2E Central Monitoring Model

FUTURE ROLES TO SUPPORT DATA COLLECTION & MONITORING



Data Engineer – Collate and Package Data

(Connect, integrate and aggregate Big Data from various sources)



Data Scientist - Turn Raw Data into Data Insights

(Apply algorithms, statistics, machine learning, & predictive modeling)



Data Analyst – Query, Summarize, and Visualize Data

(Interpret data, leverage data tools, solve problems, perform exploratory analysis)

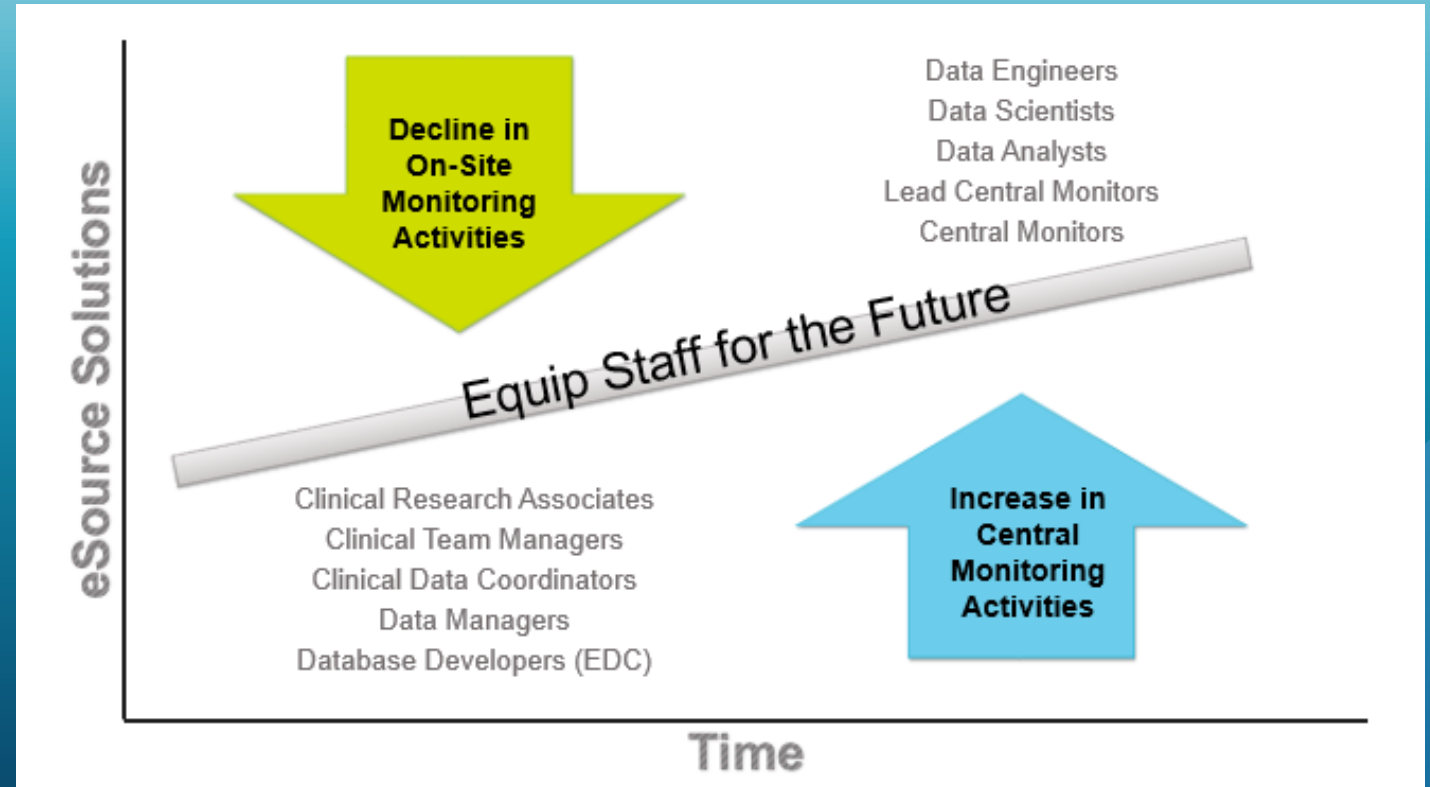


Central Monitor – Review Data and Take Action

(Apply clinical knowledge and process data according to project plans)

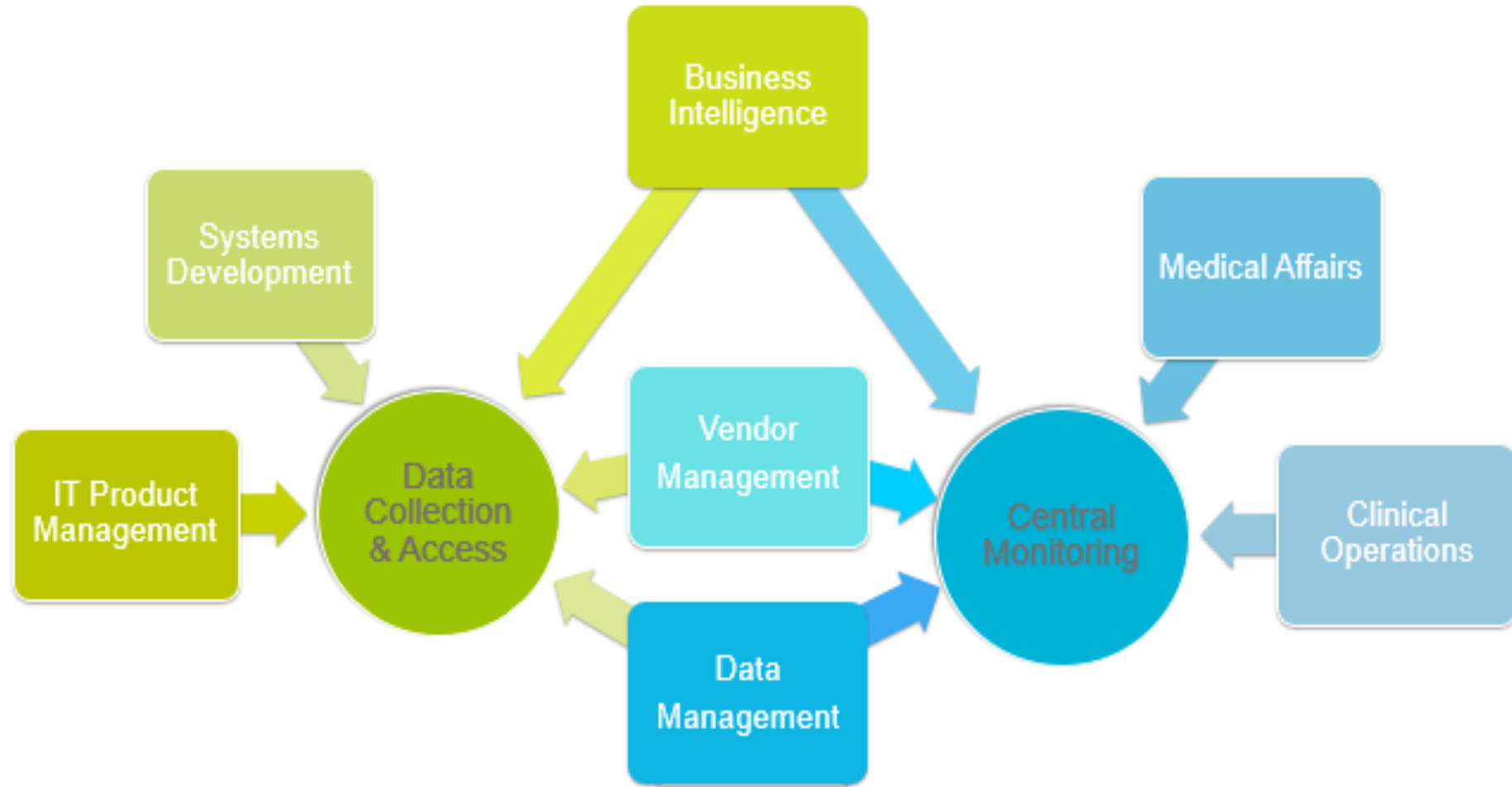
PREPARING FOR THE FUTURE: SHIFTING ROLES OVER TIME

- ▶ Move the resource needle overtime
- ▶ Establish a Clear Vision/Plan
- ▶ Strategic, incremental execution
- ▶ Prepare employees (no surprises)
- ▶ Leverage early adopters
- ▶ Cross-pollinate knowledge & skills



“TECHNOLOGY SOLUTIONS ARE INTEGRAL TO MEET THE NEEDS OF DIGITAL TRIALS; HOWEVER, THEY ALONE WILL NOT DICTATE SUCCESS. AN ORGANIZATION’S ABILITY TO RETAIN, DEVELOP, AND RECRUIT THE TALENT NEEDED TO LEVERAGE TECHNOLOGY IS WHAT WILL DICTATE SUCCESS.”

TRANSFERABLE SKILL-SETS & CROSS POLLINATION





Shared Future
Vision



Leveraging
Big Data



Empowering
Employees

KEY CONSIDERATIONS – TAKE AWAYS



QUESTIONS?