

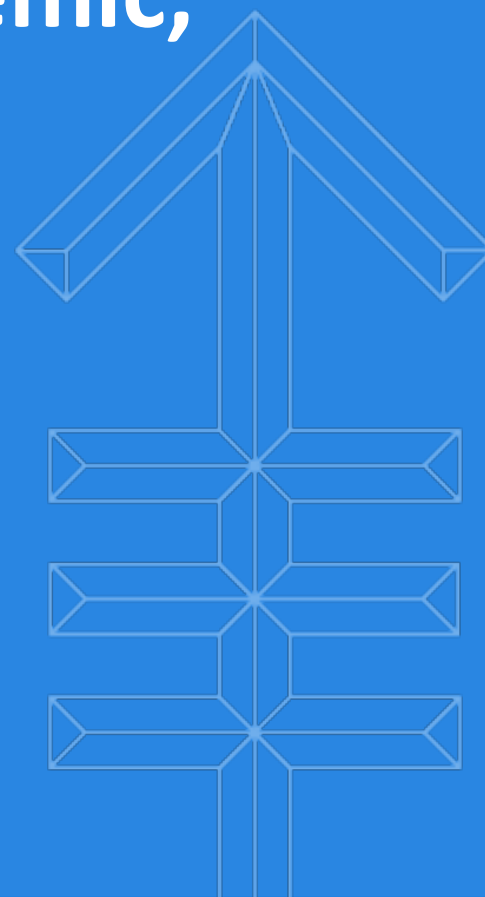


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# Virtual Clinical Trials: Monitoring and Auditing During the Pandemic, A Real World Case Study

16 December 2020

Clinical Research Administration  
Clinical Research Informatics and Technology (CRIT)  
Clinical Research Quality Assurance (CRQA)



# Speakers

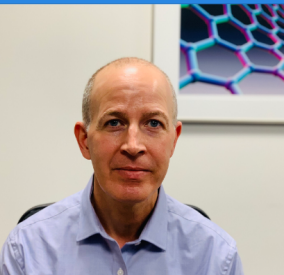


**Karima Yataghene, MD**

Clinical Research Quality Assurance Director

Karima is the director of Clinical Research Quality Assurance in the Clinical Research Compliance Unit Division of the Clinical Research Administration. Karima directs and actively manages the development and daily operations of MSK's centralized clinical research quality assurance program. Karima plans for and oversees all internal and external audits across clinical research departments and manufacturing facilities to ensure compliance with all applicable regulations. Ensures top quality research is being performed by tracking key metrics, evaluating risks, creating trend reports and implementing policies and procedures for improvement of the entire MSK clinical research portfolio of clinical trials including industrial, cooperative group, investigator initiated and externally peer reviewed trials.

Karima has more than 20 years of experience in oncology research.



**Michael Buckley, MS, MBA**

Clinical Research Informatics and Technology Enterprise Clinical Research Innovation Manager  
Co-Chair, Society for Clinical Data Management eSource Implementation Consortium

Michael is the Manager of Enterprise Innovation in the Clinical Research Informatics and Technology Division of the Clinical Research Administration. Michael's focus is on technologically innovative projects to improve the efficiency of clinical trials conduct, refine processes to simplify clinical trials data acquisition, and reduce the time and effort required for the completion of all stages of clinical trials work ranging from aligning and consenting patients through data analysis.



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# Agenda

## Virtual Monitoring and Auditing

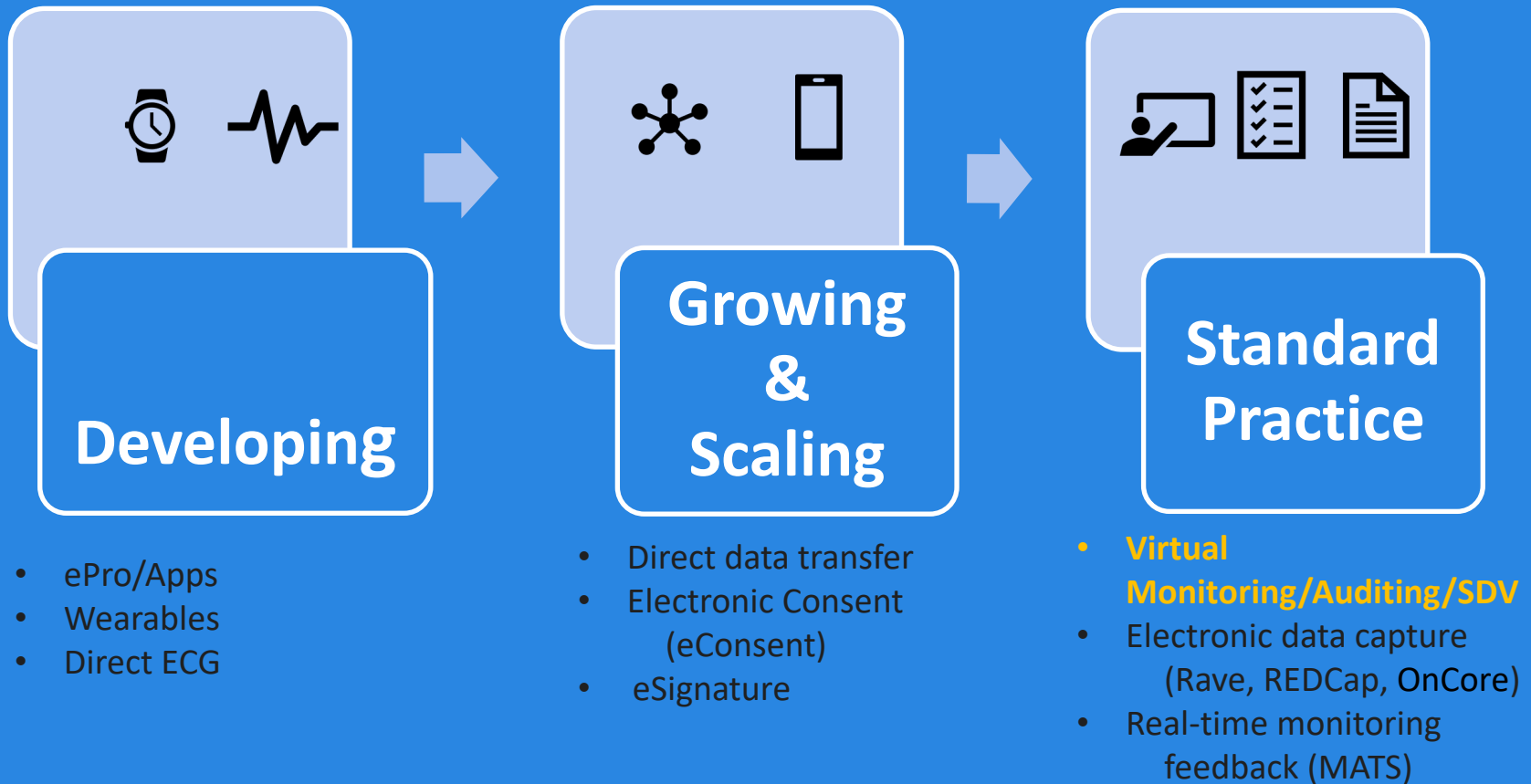
1. Background
2. Monitoring and Auditing Tracking System (MATS)
3. Workflows for Operationalization
4. eRegulatory

## Closing – Lessons Learned and Best Practices



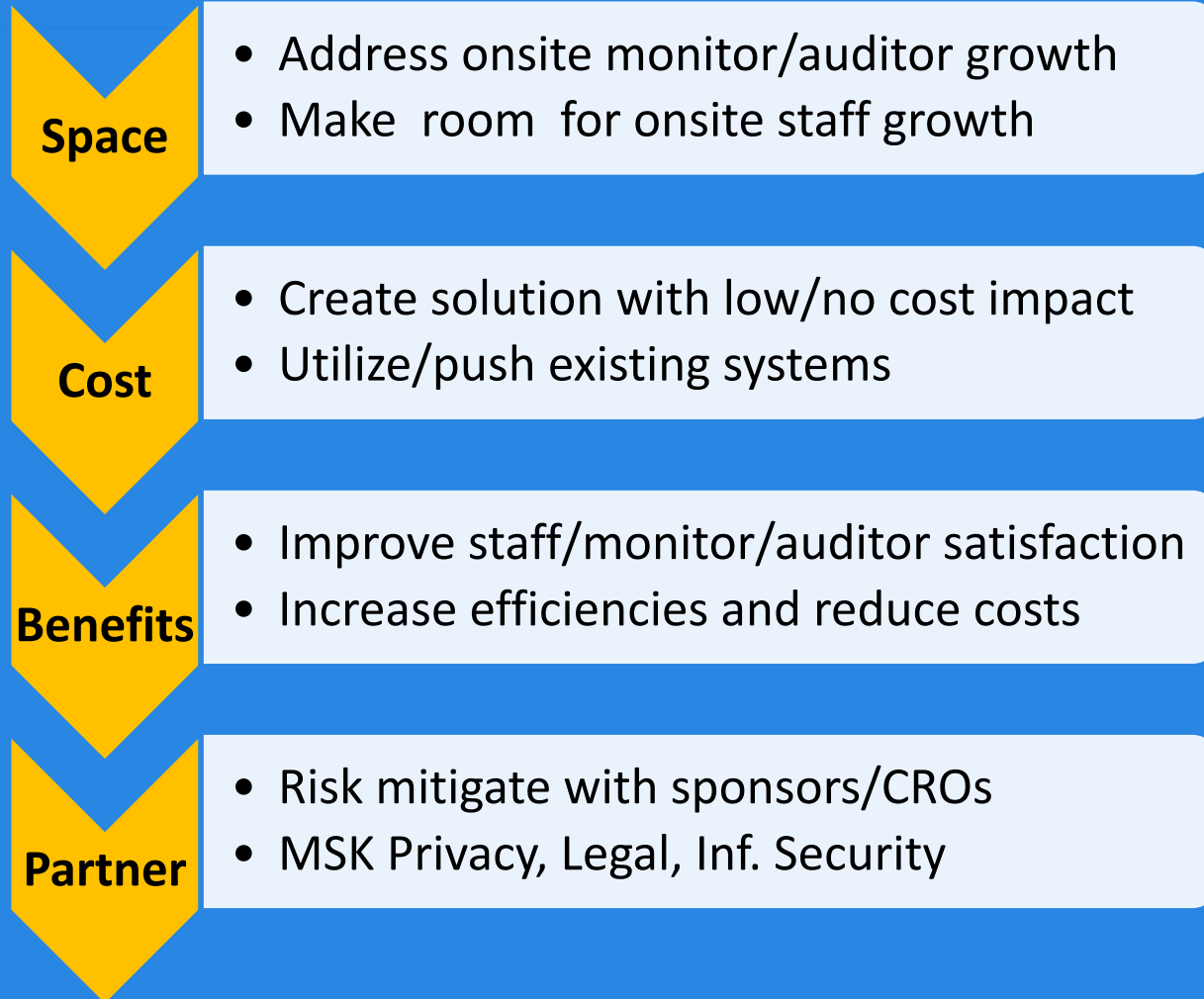
# @MSK 100% eSource Adoption Is Our Goal

MSK applies a suite of technology tools to all clinical trials



# Virtual Monitoring @ MSK: How We Started in 2011

## Charge from Leadership for Remote EMR Access



# Virtual Monitoring: Three Applications



## Virtual Monitoring

- **EMR Access**
- Went live in 2011
- 922 Monitors
- 261 Sponsors/CROs
- 100% of all active MSK trials



## MATS

- **Scheduling**
- Went live in 2015
- 2,833 (2019) → 4,501 (2020 YTD) monitors scheduled
- 220 → 607 MSK user requests

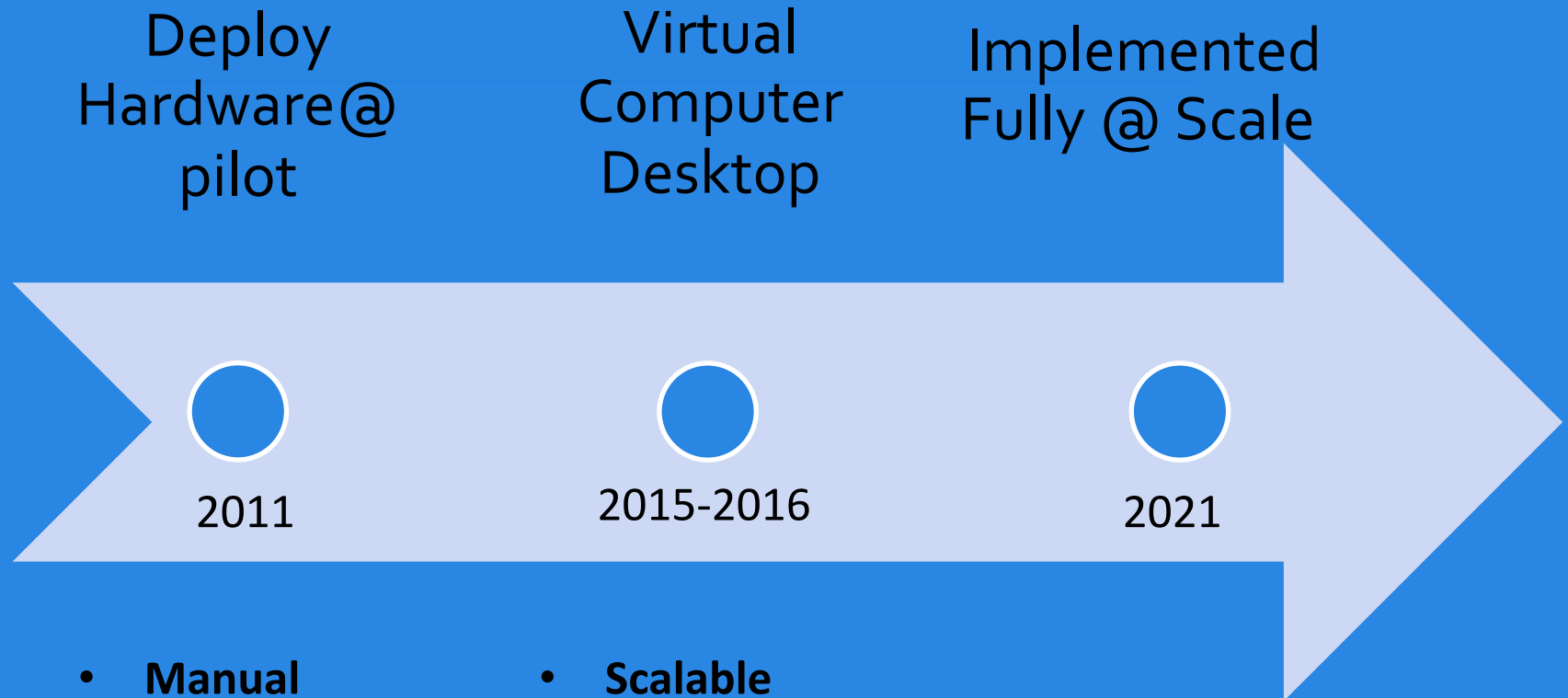


## eRegulatory

- **Regulatory Binder**
- Went live in 2015
- >20,000 monitors have used system
- >1,500 protocols



# Virtual Monitoring @ MSK: Initial Pilot to Scale



- **Manual**
- VPN
- Not scalable beyond ~100
- Audit report generation & review

- **Scalable**
- Virtual Desktop
- MATS launches
- eRegulatory launches
- Automation of audit reports and alerts



# Monitoring and Auditing Tracking System (MATS)

## What is MATS?

MATS is:

- Is a system to schedule industrial monitor/auditor visits,
- request monitor/auditor access to MSK systems during their visits,
- Is an automated online feedback system that is used to collect feedback from industrial monitors/auditors,
- share feedback with MSK study teams and MSK Clinical Research leadership in real-time, and store relevant industrial monitor/auditor visit data.

## Feedback Form

At the conclusion of the monitoring/audit visit, the system will send an email to the industrial monitor/auditor containing a link to the feedback form. The intent of the feedback form is to capture real-time feedback after each monitoring visit.





# Monitoring and Auditing Tracking System (MATS)

## MSK Staff Monitor Visit View

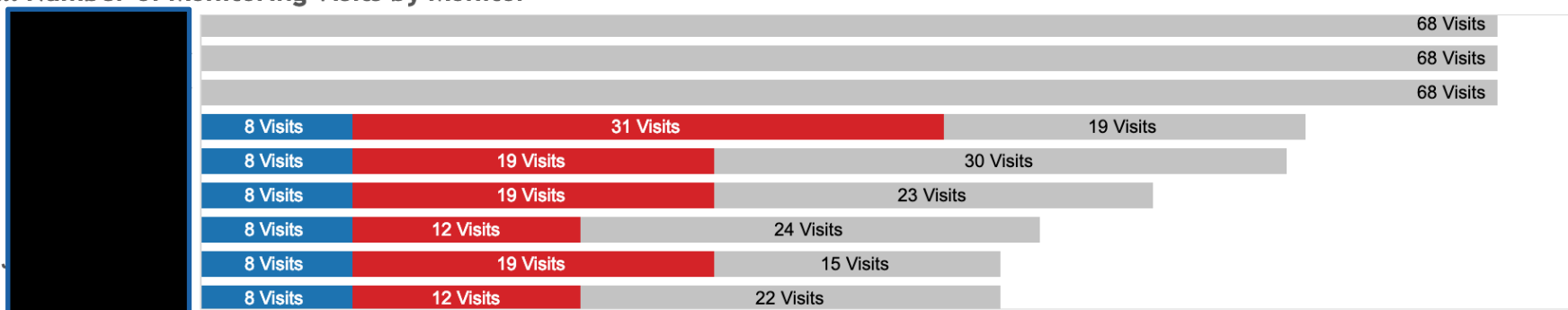
Select Visits:

May 21, 2020

October 13, 2020

■ Complete
 ■ Incomplete
 ■ Future Visit

### Overall Number of Monitoring Visits by Monitor



Protocol Sponsor

IRB#

Monitoring Company

|  |          |
|--|----------|
|  | 1 Visits |
|  | 1 Visits |
|  |          |
|  | 1 Visits |
|  | 1 Visits |
|  | 1 Visits |
|  | 1 Visits |
|  |          |
|  | 1 Visits |
|  |          |



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# Monitoring and Auditing Tracking System (MATS)

## Monitor View of Feedback Form



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### MSK Monitoring Visit Feedback Form

Please complete the MSK Monitoring Visit Feedback Form at the end of your visit. The purpose of this form is to provide you with an immediate means of communication for **significant issues/trends** identified, if present, directly to the study team and MSK Clinical Research Leadership. We acknowledge that the findings in the feedback form are preliminary and may be adjusted at a later point in time. **As such, this form is not meant to replace or be a duplicate of the Monitoring Visit Follow-Up Letter.** Significant issues not resolved in a timely manner will require a formal response from the study team to MSK Leadership.

**MSK Protocol #:** 16-392

**Sponsor:** Syneos Health

**Date of Visit:** 10/01/2020

1. Was the study team available via phone or email during the visit to answer questions?

- ☐ Yes  
☐ No

**From:** [rtmmonitor@mskcc.org](mailto:rtmmonitor@mskcc.org) <[rtmmonitor@mskcc.org](mailto:rtmmonitor@mskcc.org)>

**Subject:** [EXTERNAL] Reminder: MSK Online Monitoring Visit Feedback Form

Thank you for your recent monitoring visit at Memorial Sloan Kettering Cancer Center. Please complete the MSK Online Monitoring Visit Feedback Form for your visit on **06/24/2020** for protocol **XX-YYY**. Your feedback will ensure early transparency and real-time escalation of significant findings associated with the monitoring visit. We acknowledge that the findings in the Monitoring Visit Feedback Form are preliminary and do not in any way replace or supersede the Monitoring Visit Follow-up Letter. Please do not include any PHI in this form. The form should only take a couple of minutes to complete. The preferred web browsers for full functionality of the form are Google Chrome, Firefox or Safari. To start, please **click HERE**.

Your feedback is greatly appreciated.

Sincerely,

Clinical Research Monitoring Program  
Clinical Research Administration  
Memorial Sloan Kettering Cancer Center  
633 3rd Avenue, 15th Floor, New York, NY 10017  
646-227-6028



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# MATS and CRQA

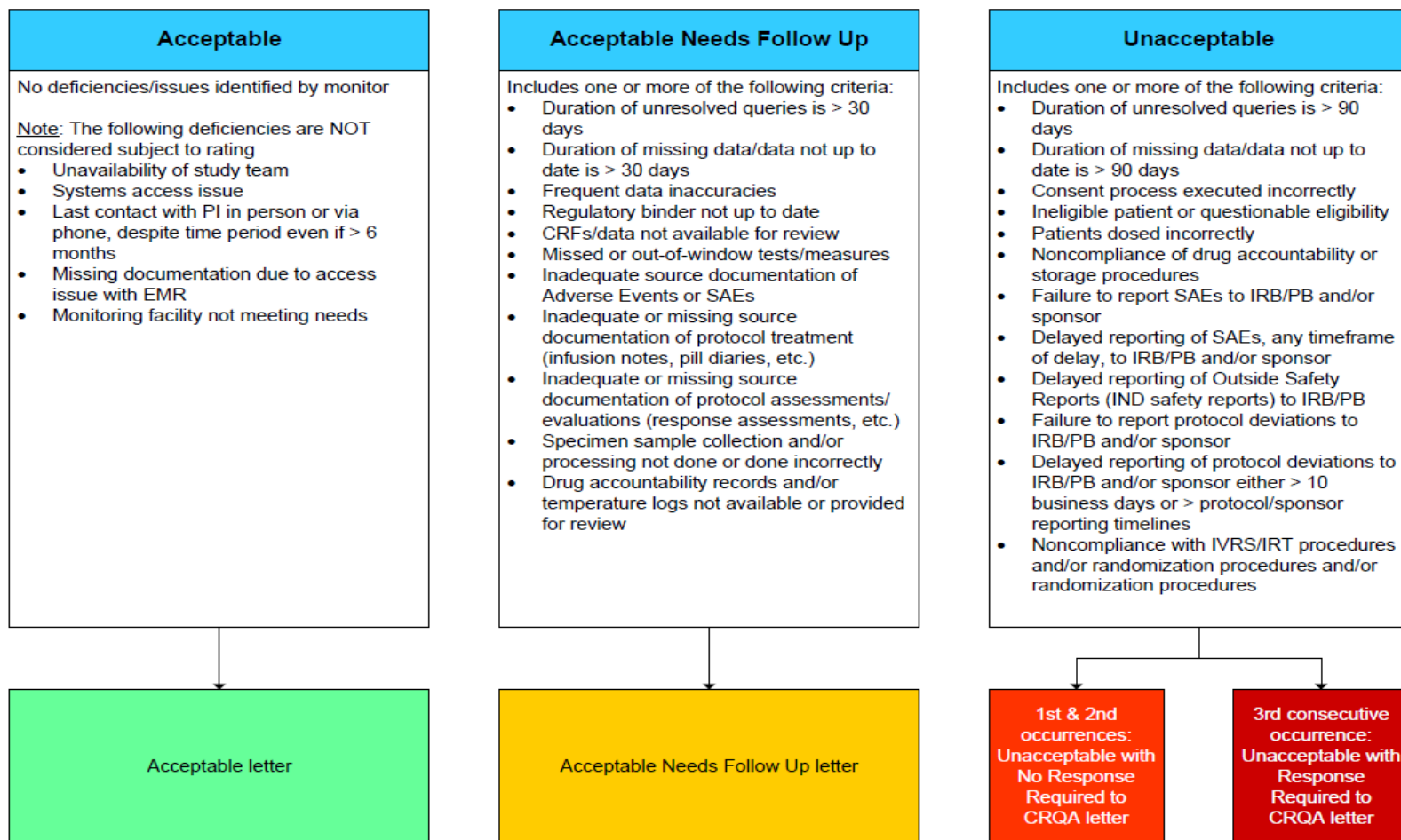
## Who monitors the MATS data?

The data is monitored by the Clinical Research Quality Assurance (CRQA) Unit. Real time review of the Monitoring Visit Feedback forms allow the CRQA to identify and communicate any significant issues/trend identified directly to the study team and MSK CR Leadership quickly.



# CRQA Rating Criteria

## MATS RATING CRITERIA FOR MONITORING VISITS

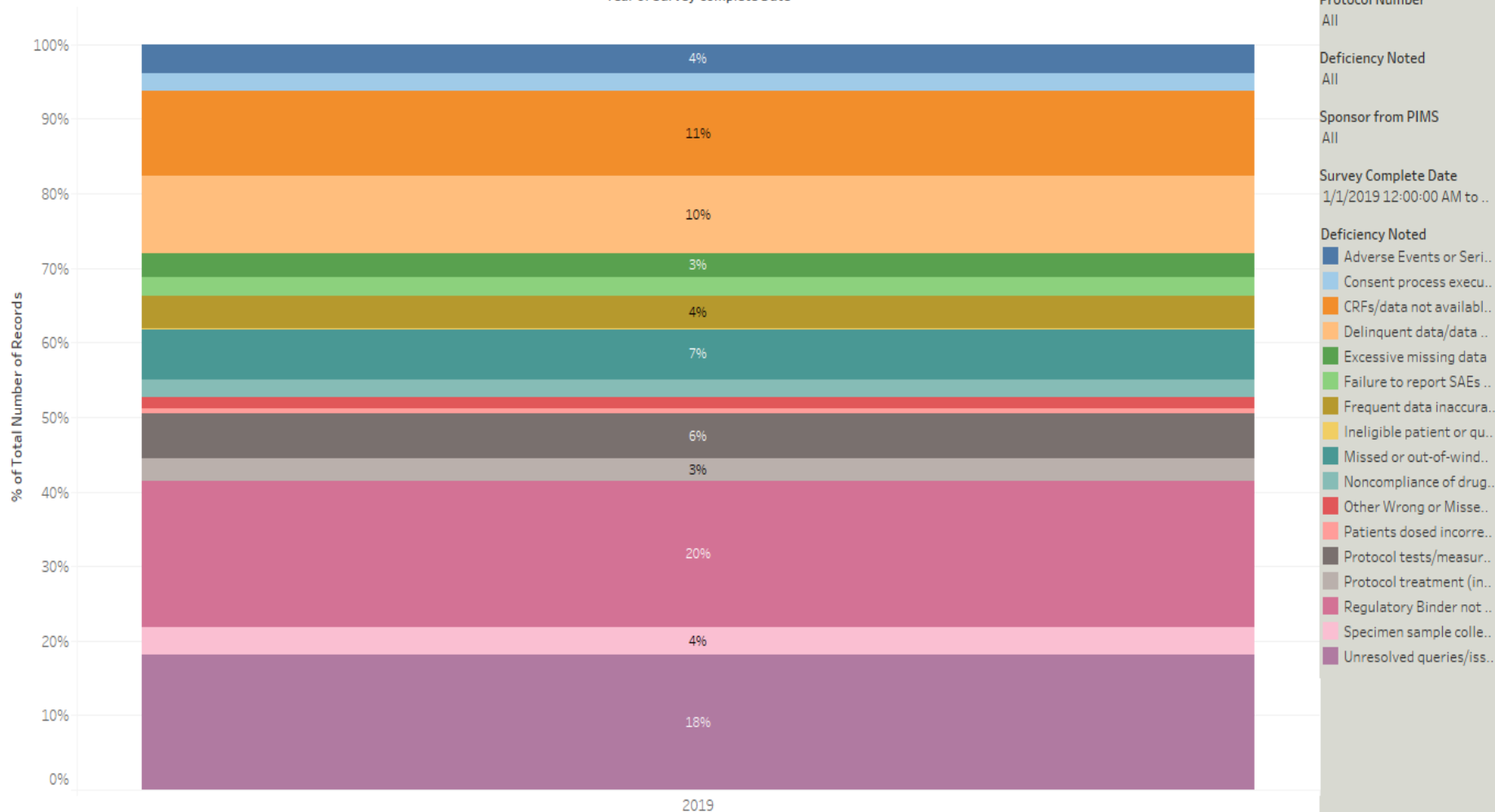




## MATS Survey Data

### Survey Sheet by Year

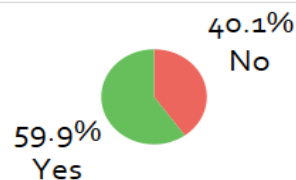
Year of Survey Complete Date



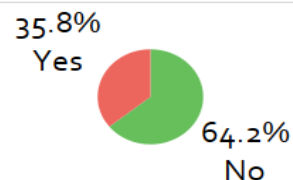


## Feedback Form Response Rate Summaries

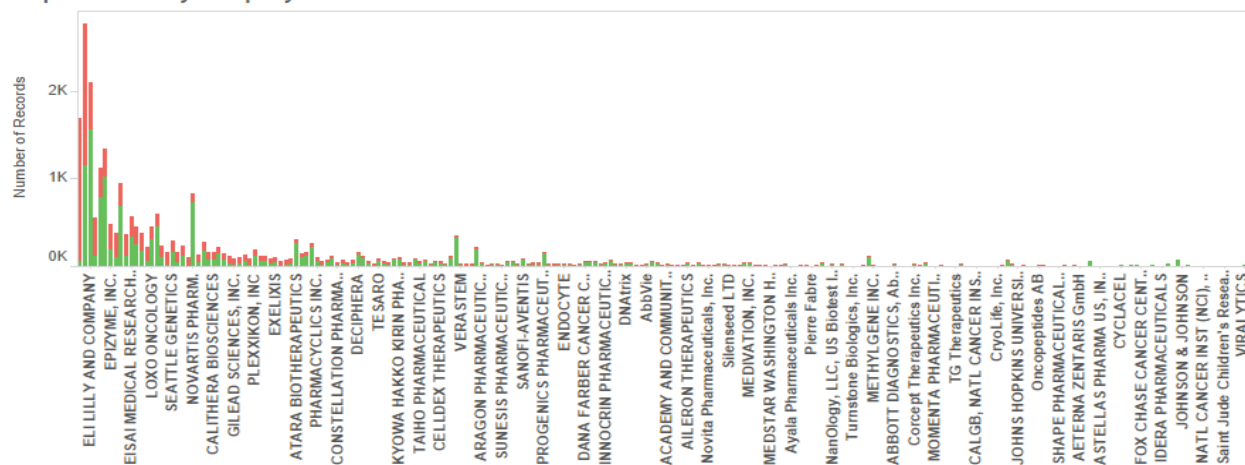
### Feedback Form Completed?



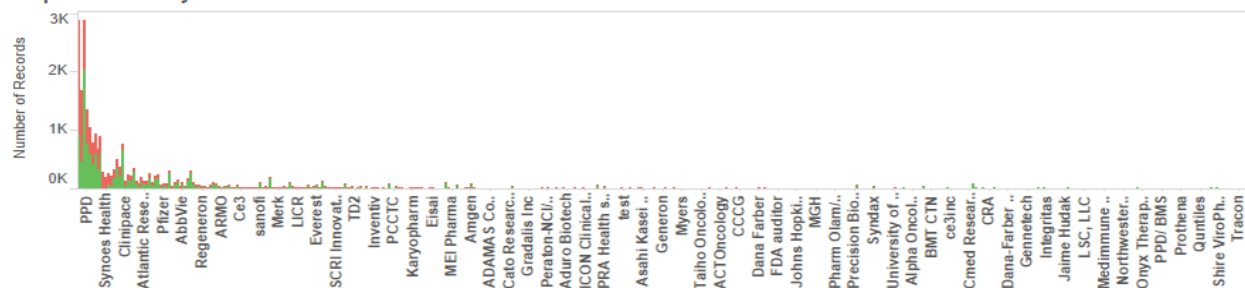
### Deficiencies identified?



### Response Rate by Company



### Response Rate By Monitor



### Filters

IRB Number  
All

Monitor Company  
All

Department/Service  
All

PI  
All

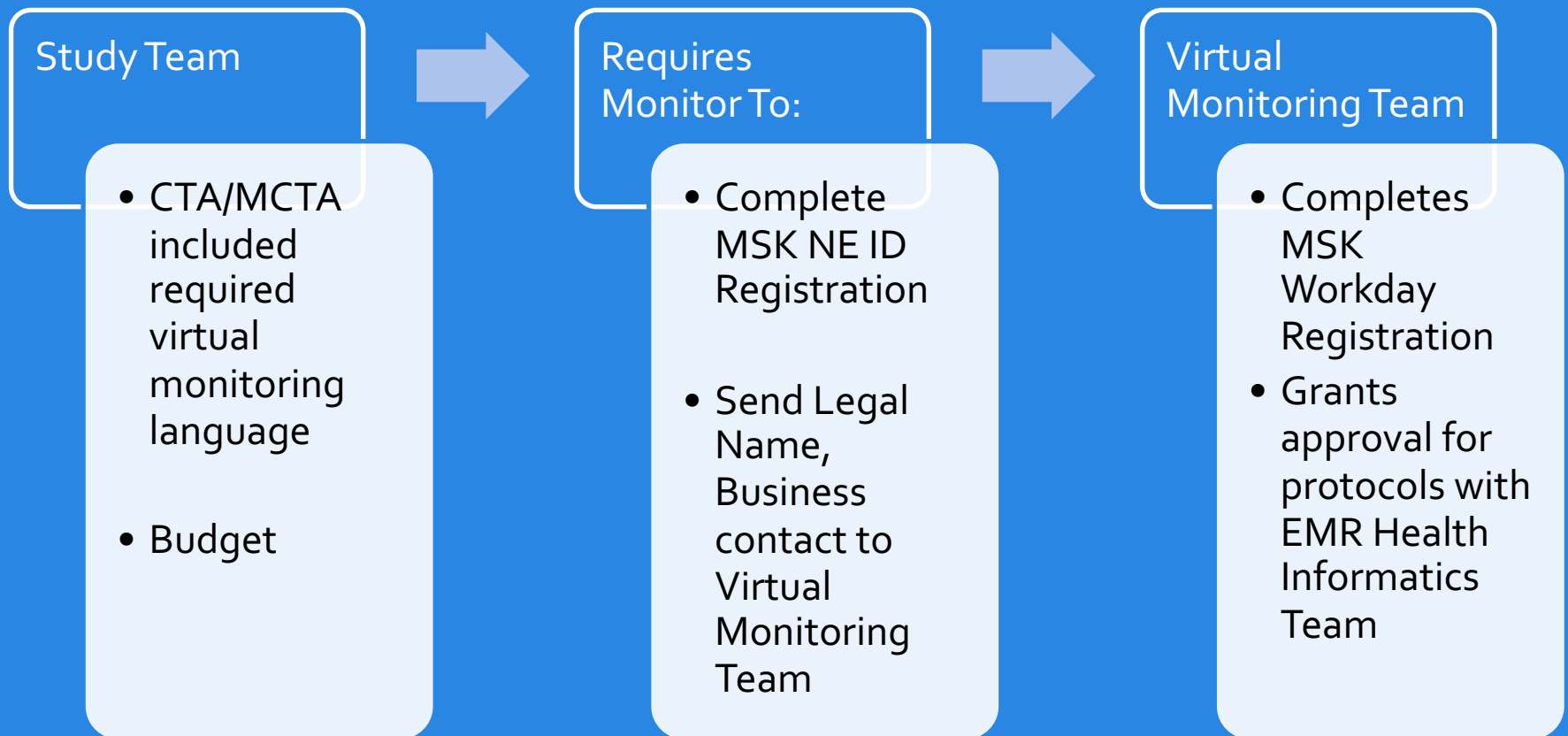
Sponsor from PIMS  
All

CreatedOn

9/2/2014 11:26:10 AM to 4/19/2019 11:24:36 AM

# Virtual Monitoring: Access to MSK's EMR Implementation

## Study Team Set Up Workflow



**Timeline: 5 business days**



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# Virtual Monitoring Implementation @ MSK

## Monitor/Auditor Non-Employee ID Registration

Task 1

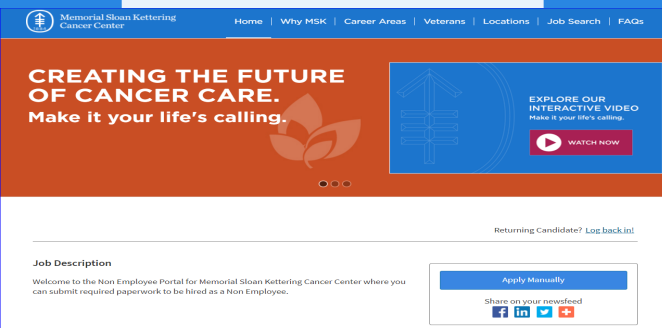
- Completes Online MSK NE ID

Task 2

- Sends Legal Name, Business contact to Virtual Monitoring Team

Leverages Existing System

- Utilize existing MSK vendor access management platform for NE ID



**Timeline: 1 day**

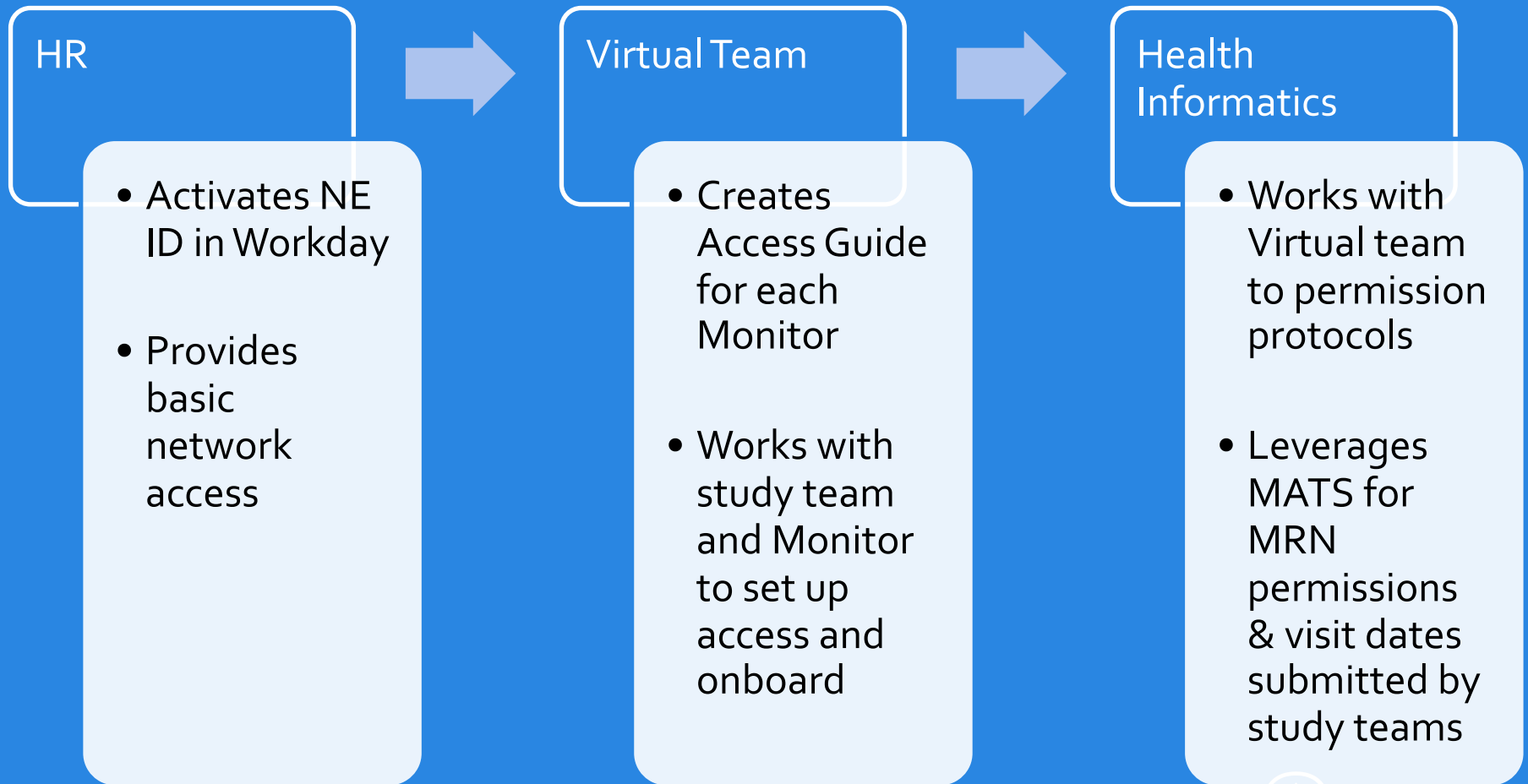


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# Virtual Monitoring Implementation @ MSK

## HR, Virtual Monitoring Team, and Health Informatics Workflow



**Timeline: 10 business days**



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# Virtual Monitoring Implementation @ MSK

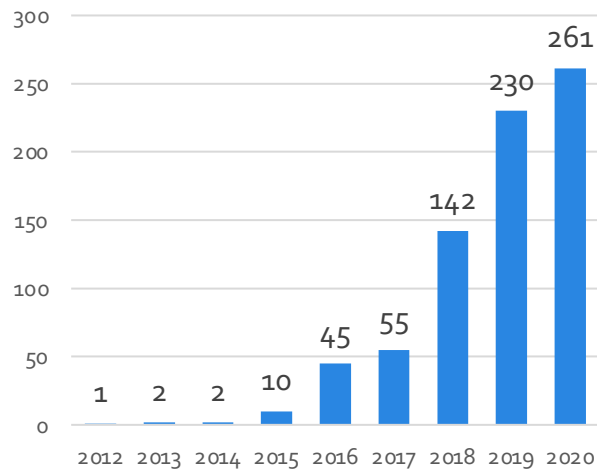
## CTA Language and Annual Maintenance



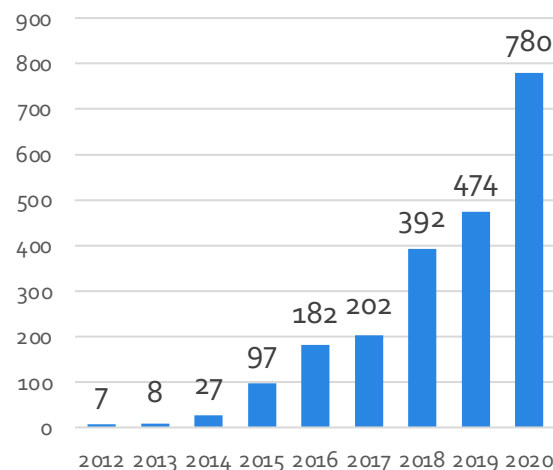
# Case Study: Virtual Monitoring Metrics and Growth

| Total Active Remote Monitors | COVID-19 Additions (included in 922 total) |
|------------------------------|--|
| 922                          | 388  |

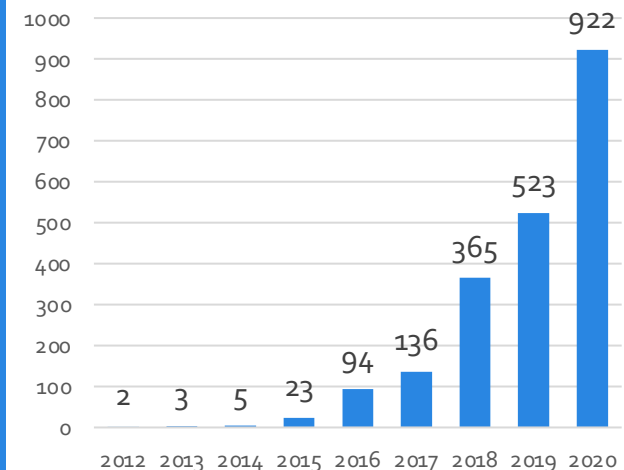
# Sponsors/CROs



# Trials Monitored



# Monitors



COVID-19 Increase: **65%**

COVID-19 increase: **76 %**



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# Case Study: Virtual Monitoring

## COVID-19 Learnings

| Year       | MSK Users Requesting Visits | Total Monitor/Auditor Visits |
|------------|-----------------------------|------------------------------|
| 2019       | 220                         | 2,833                        |
| 2020 (YTD) | 607                         | 4,501                        |
| % Increase | 176%                        | 59%                          |


### Highlights

- Ability to scale quickly during the COVID-19 pandemic
- Acted as a subject matter expert for virtual EHR access
- Shared best practices with domestic and international sites
- Conducted NCI and Cooperative Group Virtual Audits



# eRegulatory

## Monitors/Auditors see a limited screen based on the MATS DATA

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Protocol Information Management System

Monitors/Auditors

[MSK Reg Binder Access](#) [MSK Document Types](#) [MCPG Reg Binder Access](#) [MCPG Document Types](#) **Monitors/Auditors**

**Monitors/Auditors Group**

☐ Internal Monitors/Auditors

☒ External Monitors/Auditors

**Selected Person:**

test, test monitor


**Protocol Access**

| IRB Number  | Date From  | Date To    |        |
|-------------|------------|------------|--------|
| <div></div> | 04/17/2019 | 04/19/2019 | Delete |
| <div></div> | 09/13/2019 | 09/13/2019 | Delete |



# eRegulatory

Monitor view of eReg Binder. Read Only With Restricted Access



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Protocol Information Management System

Regulatory Binder

MainReg Binder

IRB NumberA3IRB-ARegulatory Binder TypeMSKLogged

Document Category/Sub Category

Original Protocol

Other Original Protocol Documents

Amendments

Other Amendment Protocol Documents

IRB Correspondence

Continuing Reviews

Investigator Brochure

Retrospective Deviations

Prospective Protocol Deviations

Other IRB Correspondence

Safety Information

SAEs Submitted to HRPP

SAEs Not submitted to HRPP

Outside Safety Correspondence Not Submitted to HRPP

Outside Safety Correspondence Submitted to HRPP

Sponsor SAE Reports

Sponsor Correspondence

Sponsor Correspondence

FDA Correspondence

Monitoring

External Monitoring

SearchOriginal Protocol

Meeting Date01/08/2019 C-N/S

Documents


|                       | Document Name                     |
|-----------------------|-----------------------------------|
| <input type="radio"/> | Sponsor ICF Template              |
| <input type="radio"/> | Misc_Mesothelioma cohort biostats |
| <input type="radio"/> | Face Sheet                        |
| <input type="radio"/> | Protocol                          |
| <input type="radio"/> | Informed Consent                  |
| <input type="radio"/> | Lab Manual                        |
| <input type="radio"/> | Patient Emergency Card            |
| <input type="radio"/> | Pill Diary                        |

Review Letters

|                       | Document Name                   |
|-----------------------|---------------------------------|
| <input type="radio"/> | Conditions Not Satisfied Letter |
| <input type="radio"/> | Initial Approval Letter         |

# Virtual Monitoring @ MSK: 2011 to Present

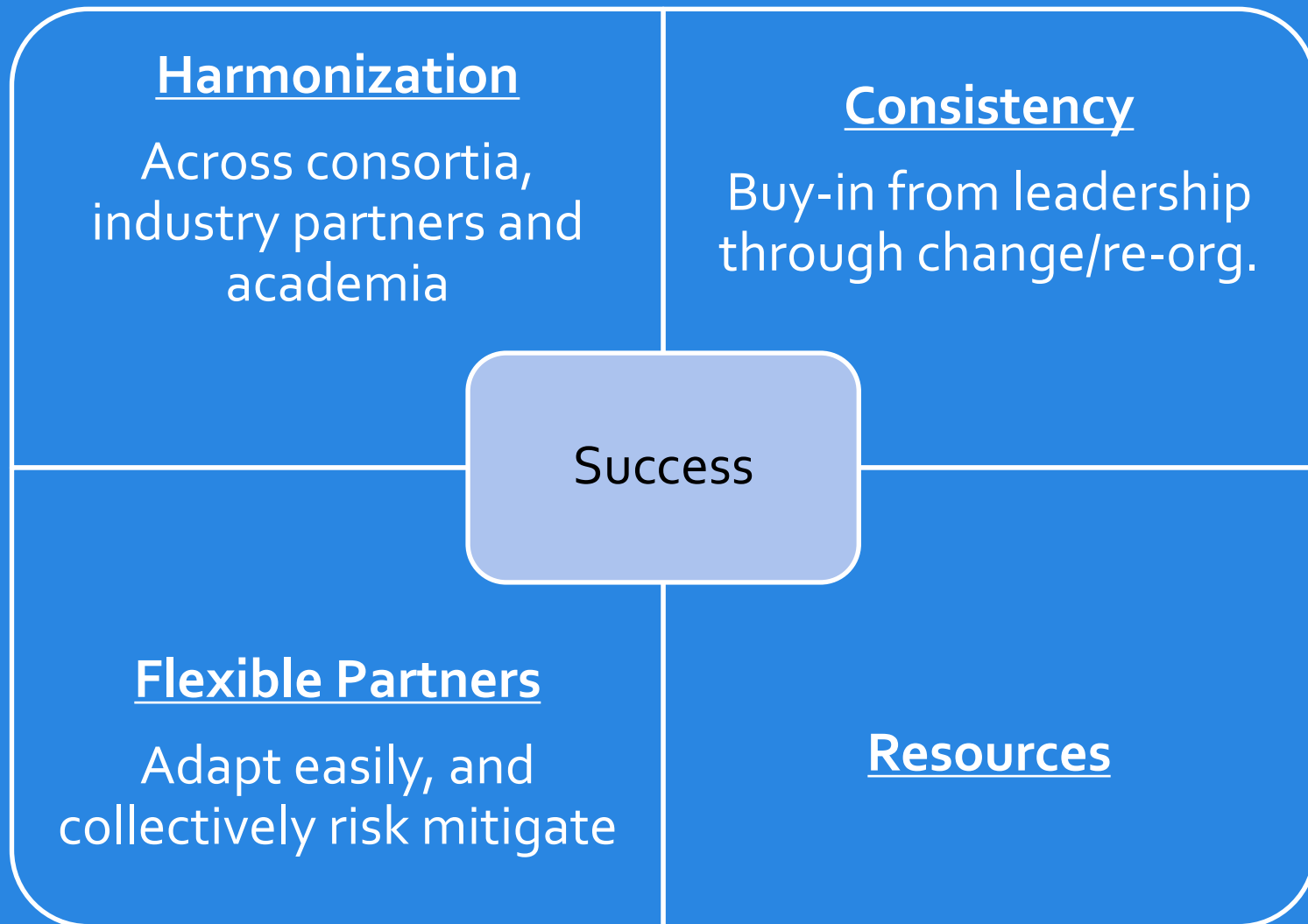
## Return On Investment



|                |   |
|----------------|---|
| Productivity   | <ul style="list-style-type: none"><li>• Reclaimed 3h per visit for monitor and research associates, from 4h average → 1h fixed apt.</li></ul>   |
| Data Readiness | <ul style="list-style-type: none"><li>• Increased the turnaround time of query resolution from 2-4 weeks to 5 days</li><li>• Increase data verification visits; not space dependent</li></ul> |
| Satisfaction   | <ul style="list-style-type: none"><li>• Monitors provided protocol level access for trending AEs, Rxns, Dosing</li><li>• Site personnel</li></ul>   |
| Cost Savings   | <ul style="list-style-type: none"><li>• 2012 sponsor productivity analysis showed a per monitor per protocol cost savings of \$17.5K/year</li></ul>   |
|                |   |
|                |   |
|                |   |



# Closing- Lessons Learned





# Thank You

## Clinical Research Administration

- Dr. Eric Cottingham
- Dr. Paul Sabbatini
- Dr. Stephanie Terzulli
- Joseph Lengfellner
- Collette Houston
- Nicholas Cimaglia

## Clinical Research Quality Assurance

- Francine Puma
- Adrian Granobles
- Kamala Mantha-thaler

## Research Technology Management

- Lee Stetson

## Information Security

- Michael Czumak

## Clinical Research Informatics and Technology

- Kristopher Kaufman
- Brian Seko
- Matt Koch
- Marcia Latif
- Dawn Caron
- Joshua Levine
- Hector Pacheco

## Health Informatics

- Mary Mitchell
- Jay Washington
- Cynthia Hutchinson

## Privacy

- Kristen Ahearn
- Jessica Palla
- Joanna Halperin

