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

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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.
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 applies a suite of technology tools to all clinical trials

Developing
- ePro/Apps
- Wearables
- Direct ECG

Growing & Scaling
- Direct data transfer
- Electronic Consent (eConsent)
- eSignature

Standard Practice
- Virtual Monitoring/Auditing/SDV
- Electronic data capture (Rave, REDCap, OnCore)
- Real-time monitoring feedback (MATS)

@MSK 100% eSource Adoption Is Our Goal
Virtual Monitoring @ MSK: How We Started in 2011 Charge from Leadership for Remote EMR Access

**Space**
- Address onsite monitor/auditor growth
- Make room for onsite staff growth

**Cost**
- Create solution with low/no cost impact
- Utilize/push existing systems

**Benefits**
- Improve staff/monitor/auditor satisfaction
- Increase efficiencies and reduce costs

**Partner**
- Risk mitigate with sponsors/CROs
- MSK Privacy, Legal, Inf. Security
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
  - 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

- **Deploy Hardware @ pilot**
- **Virtual Computer Desktop**
- **Implemented Fully @ Scale**

- **2011**
- **2015-2016**
- **2021**

- **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:

- A system to schedule industrial monitor/auditor visits,
- Request monitor/auditor access to MSK systems during their visits,
- 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

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#### Overall Number of Monitoring Visits by Monitor

<table>
<thead>
<tr>
<th>Visits</th>
<th>Complete</th>
<th>Incomplete</th>
<th>Future Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>68 Visits</td>
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<td></td>
<td></td>
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<tr>
<td>68 Visits</td>
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<tr>
<td>68 Visits</td>
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**Protocol Sponsor**

**IRB#**

**Monitoring Company**

<table>
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<th>Visits</th>
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<tbody>
<tr>
<td>1 Visits</td>
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<td>1 Visits</td>
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<td>1 Visits</td>
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<td>1 Visits</td>
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**Memorial Sloan Kettering Cancer Center**
Monitoring and Auditing Tracking System (MATS)

Monitor View of Feedback Form

From: rtmmonitor@mskcc.org <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

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
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

MATIS RATING CRITERIA FOR MONITORING VISITS

**Acceptable**
- No deficiencies/issues identified by monitor

**Note:** The following deficiencies are NOT considered subject to rating
- Unavailability of study team
- Systems access issue
- Last contact with PI in person or via phone, despite time period even if > 6 months
- Missing documentation due to access issue with EMR
- Monitoring facility not meeting needs

**Acceptable Needs Follow Up**
- Includes one or more of the following criteria:
  - Duration of unresolved queries is > 30 days
  - Duration of missing data/data not up to date is > 30 days
  - Frequent data inaccuracies
  - Regulatory binder not up to date
  - CRFs/data not available for review
  - Missed out-of-window tests/measures
  - Inadequate source documentation of Adverse Events or SAEs
  - Inadequate or missing source documentation of protocol treatment (infusion notes, pill diaries, etc.)
  - Inadequate or missing source documentation of protocol assessments/evaluations (response assessments, etc.)
  - Specimen sample collection and/or processing not done or done incorrectly
  - Drug accountability records and/or temperature logs not available or provided for review

**Unacceptable**
- Includes one or more of the following criteria:
  - Duration of unresolved queries is > 90 days
  - Duration of missing data/data not up to date is > 90 days
  - Consent process executed incorrectly
  - Ineligible patient or questionable eligibility
  - Patients dosed incorrectly
  - Noncompliance of drug accountability or storage procedures
  - Failure to report SAEs to IRB/PB and/or sponsor
  - Delayed reporting of SAEs, any timeframe of delay to IRB/PB and/or sponsor
  - Delayed reporting of Outside Safety Reports (IND safety reports) to IRB/PB
  - Failure to report protocol deviations to IRB/PB and/or sponsor
  - Delayed reporting of protocol deviations to IRB/PB and/or sponsor either > 10 business days or > protocol/sponsor reporting timelines
  - Noncompliance with IVRS/IRT procedures and/or randomization procedures and/or randomization procedures

- **1st & 2nd occurrences:** Unacceptable with No Response Required to CRQA letter
- **3rd consecutive occurrence:** Unacceptable with Response Required to CRQA letter
Virtual Monitoring: Access to MSK’s EMR Implementation

Study Team Set Up Workflow

Study Team
- CTA/MCTA included required virtual monitoring language
- Budget

Requires Monitor To:
- Complete MSK NE ID Registration
- Send Legal Name, Business contact to Virtual Monitoring Team

Virtual Monitoring Team
- Completes MSK Workday Registration
- Grants approval for protocols with EMR Health Informatics Team

Timeline: 5 business days
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
Virtual Monitoring Implementation @ MSK

HR, Virtual Monitoring Team, and Health Informatics Workflow

**HR**
- Activates NE ID in Workday
- Provides basic network access

**Virtual Team**
- Creates Access Guide for each Monitor
- Works with study team and Monitor to set up access and onboard

**Health Informatics**
- Works with Virtual team to permission protocols
- Leverages MATS for MRN permissions & visit dates submitted by study teams

Timeline: 10 business days
Virtual Monitoring Implementation @ MSK

CTA Language and Annual Maintenance

CTA/MCTA Legal Language for Virtual Monitoring

Annual Monitoring & Auditing Maintenance Fee

Access
Case Study: Virtual Monitoring Metrics and Growth

<table>
<thead>
<tr>
<th>Total Active Remote Monitors</th>
<th>COVID-19 Additions (included in 922 total)</th>
</tr>
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<tbody>
<tr>
<td>922</td>
<td>388</td>
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COVID-19 Increase: 65%

COVID-19 Increase: 76%
# Case Study: Virtual Monitoring

## COVID-19 Learnings

<table>
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<tr>
<th>Year</th>
<th>MSK Users Requesting Visits</th>
<th>Total Monitor/Auditor Visits</th>
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<tbody>
<tr>
<td>2019</td>
<td>220</td>
<td>2,833</td>
</tr>
<tr>
<td>2020 (YTD)</td>
<td>607</td>
<td>4,501</td>
</tr>
<tr>
<td>% Increase</td>
<td>176%</td>
<td>59%</td>
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**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
Monitors/Auditors see a limited screen based on the MATS DATA
Monitor view of eReg Binder. Read Only With Restricted Access
### Virtual Monitoring @ MSK: 2011 to Present

#### Return On Investment

<table>
<thead>
<tr>
<th>Category</th>
<th>Benefits</th>
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<tbody>
<tr>
<td><strong>Productivity</strong></td>
<td>• Reclaimed 3h per visit for monitor and research associates, from 4h average → 1h fixed apt.</td>
</tr>
</tbody>
</table>
| **Data Readiness** | • Increased the turnaround time of query resolution from 2-4 weeks to 5 days  
                   • Increase data verification visits; not space dependent |
| **Satisfaction** | • Monitors provided protocol level access for trending AEs, Rxns, Dosing  
                   • Site personnel |
| **Cost Savings** | • 2012 sponsor productivity analysis showed a per monitor per protocol cost savings of $17.5K/year |
Harmonization
Across consortia, industry partners and academia

Consistency
Buy-in from leadership through change/re-org.

Flexible Partners
Adapt easily, and collectively risk mitigate

Resources

Success
Thank You

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Information Security
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