Open Clinica
RBM Risk Based Monitoring

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Was created by experts in the fields of IT, Clinical Research and Business Information Systems with the aim of offering its customers innovative solutions and advice specializing in:

- **Management of Clinical Trials**
- **Information Systems applied to Clinical Research**

The experience provided by the company consultants is the result of decades of collaboration with Companies and Institutions of the Pharmaceutical, Medical and Clinical Research sectors.
News and Updates

Get Started!

Well known UI
Create form
Check system
Reliable architecture
Easy learning
OUR IDEA

Development on OpenClinica to manage new specific features:

- Assessment and categorization of risk
- Create MRF Monitoring Report Form
- Manage Monitoring Activity
Risk-based monitoring

- SDV/SDR*  
- Review of critical processes  
  - Protecting subjects  
  - Data integrity  
  - GCP and protocol compliance  
- Drug Accountability  
- Build relationship  
- Training  
- Review of ISF

On-site monitoring

- Remote/Off-site/In-house review of clinical data (on-line) and operational data (Risk Indicators)  
- Remote visits (calls)  
- Remote SDV

Centralized/remote monitoring

- Centralized review of clinical data (through listings or reports)  
- Centralized Statistics

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PWC ANALYSIS ON SAVING

Cost: Initial estimates show potential of risk-based monitoring to save 15 to 20% in study portfolio costs

Percent savings of risk-based monitoring compared with current monitoring:

- Site monitoring & auditing: 25%
- Project management: 20%
- Site management: 5%
- Data processing and management: 20%
- Investigator setup: 10%
- Planning and start-up: -2%
- Safety: 0%

Legend:
- Red: Current costs
- Gray: Risk-based monitoring costs
INDUSTRY SHIFT TO RISK-BASED MONITORING

Marcus Thorton Senior Director at Medidata at 50th DIA Conference in San Diego:

“Research company in 2014 are expected to spend up to $7,5bn on SDV”

By Zachary Brennan, 19-Jun-2014


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MAIN STEPS FOR IMPLEMENTING RBM

Set-up phase: TAILORING STRATEGY

1) Quality by Design (QbD)
2) Risk assessment (study and sites)
3) Define critical data and processes
4) Define Risk Indicators and thresholds
5) Define monitoring strategy based on risk assessments
   • On-site monitoring
   • Remote monitoring
   • Centralized monitoring

Experimental phase: IMPLEMENTATION & FOLLOW-UP

Apply tailored strategy:

1) On-site visits (when triggered by risk indicator for critical processes and TSDV)
2) Remote monitoring
   • Off-site review of clinical data
   • Remote visits (calls)
   • Remote SDV
3) Centralized monitoring
   • Review of risk indicators
   • Holistic review of clinical data

After closure: EVALUATION

1) Quality
   • major/critical finding/sites
   • significant protocol deviations/site
   • unreported, confirmed SAEs
2) Timelines
   • days from data entry to monitoring
   • days from visit to CRF data entry
   • days from query open to close
3) Efficiency
   • Monitoring cost /site
   • Interval between On-site visits/site
TRANSCELERATE TOOLS

RACT

Risk Assessment and Categorization Tool
V2 11/apr/2014

IQRMP

Integrated Quality & Risk Management Plan

© OpenClinica
Open Source for Clinical Research

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## RBM RACT TOOL

<table>
<thead>
<tr>
<th>Category</th>
<th>Objective</th>
<th>Questions for Discussion</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>Determine any known risks for subject safety</td>
<td>If your company has standard processes for determination of potential or identified safety risks, then this can serve as input to the overall risk category instead of below the separate questions</td>
<td>Identified risks from the Medical Surveillance Team (MST) Chair with which have predetermined rules for determining safety risk with confirmation from the Medical Leader.</td>
</tr>
<tr>
<td>Safety</td>
<td>Per the Medical Surveillance Team (MST) Chair with Medical Leader confirm what is the safety risk to the subject?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Overall Risk Level:

<table>
<thead>
<tr>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Impact 3 point scale (blue line = category summary)</td>
<td>Probability 3 point scale (blue line = category summary)</td>
<td>Detectability point scale (blue line = category summary)</td>
<td>3</td>
<td>Total Category Risk Score</td>
</tr>
<tr>
<td>2</td>
<td>Category Weighting 0.1 - 1.0 (summary rating only 1.0 is default)</td>
<td>Program/protocol risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td></td>
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<tr>
<td>5</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>High (3)</th>
<th>Medium (2)</th>
<th>Medium to detect (2)</th>
<th>12</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Notes:**
- Difficult to detect (3)
- Medium to detect (2)
- Easy to detect (1)
## CATEGORIZATION

<table>
<thead>
<tr>
<th>Monitoring Activity*</th>
<th>High Risk</th>
<th>Medium Risk</th>
<th>Low Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation and Review of Data (Central/Off-site)</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>SDV of Critical Data for First Randomized Subject</td>
<td>&gt;75 - 100%</td>
<td>&gt;50 - 75%</td>
<td>0 - 50%</td>
</tr>
<tr>
<td>SDV of Critical Data for Subsequent Randomized Subjects</td>
<td>&gt;15 - 25%</td>
<td>&gt;5 - 15%</td>
<td>0 - 5%</td>
</tr>
<tr>
<td>SDR of Critical Data for First Randomized Subject</td>
<td>&gt;75 - 100%</td>
<td>&gt;25 - 75%</td>
<td>0 - 25%</td>
</tr>
<tr>
<td>SDR of Critical Data for Subsequent Randomized Subjects</td>
<td>&gt;25 - 40%</td>
<td>&gt;10 - 25%</td>
<td>0 - 10%</td>
</tr>
<tr>
<td>Informed Consent Review</td>
<td>&gt;75 - 100%</td>
<td>&gt;50 - 75%</td>
<td>20 - 50%</td>
</tr>
</tbody>
</table>

* As the risk level may vary across the various **stages** of the study, the type, amount, and location of monitoring activities may also vary
DataRiver is specialized in designing and developing solutions for Data Integration to solve problems of inconsistency, heterogeneity and quality of the data to be integrated.

DataRiver offers cutting-edge solutions and specialized consulting services for problems in the fields of Clinical Data Management, Data Integration, Semantic Web and Business Intelligence.

DataRiver develops web application and mobile application able to interface and exchange information with clinical data management systems.
New Platform based on OpenClinica

Main modules:
- Risk Assessment and Categorization Tool
- MRF Monitoring Report Form

Actual stage: Prototype

First release est. Q4’14
FEATURES

- Manage the RACT TOOL as a CRF
- Create Monitoring Report as a CRF ➔ MRF
- Correlate the RACT questions and risk level with the Report of Monitoring
- Let CRA fill in monitoring report through MRF in system with a specific database
- Create Edit Checks and Queries to address properly the on-site, off-site and centralized monitoring report
Changes applied to:
• JSP
• Translation properties file (i18n)
• javascripts

✓ changes are limited to GUI: database and software application core architecture are not modified
✓ friendly interface for users who are already familiar with OpenClinica
✓ easy to move and migrate changes to new releases
**Title:** 6 Data Collection CRF source

**Instructions:** Assess the integrity of the data based on data collection methods

<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Manual</th>
<th>Electronic</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>Is the data collected?</td>
<td>✔️ Manually</td>
<td>✔️ Electronically</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are there any data collected using eSource (direct data entry)?</td>
<td>✔️ Yes</td>
<td>✗ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are CRF data collected using EDC?</td>
<td>✔️ Yes</td>
<td>✗ No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMPACT:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PROBABILITY:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DETECTABILITY:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6.2

What is the time lapse between data entry and availability for central review? (Days)

<table>
<thead>
<tr>
<th>IMPACT:</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROBABILITY:</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>DETECTABILITY:</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
</tbody>
</table>
Title: 5 Technology

Instructions: What level of technology competence is required for a successful study?

Is there a new tool/device being implemented to capture data?

Impact:
- high
- medium
- low

Probability:
- high
- medium
- low

Detectability:
- high
- medium
- low
Will multiple data systems be used requiring data transfer and integration?

**IMPACT:**
- high
- medium
- low

**PROBABILITY:**
- high
- medium
- low

**DETECTABILITY:**
- high
- medium
- low

Determine if the amount of data will impact the ability to perform central monitoring.

**IMPACT:**
- high
- medium
- low

**PROBABILITY:**
- high
- medium
- low

**DETECTABILITY:**
- high
- medium
- low
**Title:** 7 Endpoints

**Instructions:** Determine if the method for capturing endpoints will affect data integrity?

How will the primary and secondary endpoints be collected?

- **IMPACT:**
  - high
  - medium
  - low

- **PROBABILITY:**
  - high
  - medium
  - low

- **DETECTABILITY:**
  - high
  - medium
  - low

Is it an event driven or outcome study?

- **IMPACT:**
  - high
  - medium
  - low

- **PROBABILITY:**
  - high
  - medium
  - low

- **DETECTABILITY:**
  - high
  - medium
  - low
Patient Enrolment v.1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

<table>
<thead>
<tr>
<th>Title: Patient Enrolment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question #1</strong></td>
</tr>
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</table>

Is the actual enrolment rate in line with the expected rate?
- Yes
- No*
- Unk = item not verified during monitoring visit

If the chosen answer is marked with an asterisk, describe issues and actions taken/ to be taken

If any issue was unresolved at the previous visit, report the issue description again on the present report and tick the appropriate outcome box

<table>
<thead>
<tr>
<th>Describe issue:</th>
<th>Actions taken or to be taken:</th>
<th>Status:</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Ongoing</td>
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<tr>
<td></td>
<td></td>
<td>Resolved</td>
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Comments:
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<td>Yes* Unk = item not verified during monitoring visit</td>
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<td>No Unk</td>
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**Comments:**

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<tbody>
<tr>
<td>Have any discrepancies with respect to the SUSAR Checklist been noted?</td>
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**Comments:**

<table>
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<th>Question #3</th>
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<tbody>
<tr>
<td>If required by local regulations: have all SUSARs been forwarded to the Ethics Committee?</td>
</tr>
<tr>
<td>Yes Unk = item not verified during monitoring visit</td>
</tr>
<tr>
<td>No* Unk</td>
</tr>
<tr>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
### Question #1

**Have any discrepancies with respect to the Regulatory Documents Checklist been noted?**

- [ ] Yes* Unk = item not verified during monitoring visit
- [ ] No
- [ ] Unk

**Impact:**
- [ ] High
- [ ] Medium
- [ ] Low

**Probability:**
- [ ] High
- [ ] Medium
- [ ] Low

**Detectability:**
- [ ] High
- [ ] Medium
- [ ] Low

*If the chosen answer is marked with an asterisk, describe issues and actions taken/to be taken*

If any issue was unresolved at the previous visit, report the issue description again on the present report and tick the appropriate outcome box.

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<thead>
<tr>
<th>Comments:</th>
</tr>
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<tbody>
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</table>

### Question #2

**Have any discrepancies with respect to the SUSAR Checklist been noted?**

- [ ] Yes* Unk = item not verified during monitoring visit
- [ ] No
- [ ] Unk

**Impact:**
- [ ] High
- [ ] Medium
- [ ] Low

**Probability:**
- [ ] High
- [ ] Medium
- [ ] Low

**Detectability:**
- [ ] High
- [ ] Medium
- [ ] Low

*If the chosen answer is marked with an asterisk, describe issues and actions taken/to be taken*

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<thead>
<tr>
<th>Comments:</th>
</tr>
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</table>

### Question #3

**If required by local regulations: have all SUSARs been forwarded to the Ethics Committee?**

- [ ] Yes
- [ ] No*
- [ ] Unk
- [ ] Not Applicable

**Impact:**
- [ ] High
- [ ] Medium
- [ ] Low

**Probability:**
- [ ] High
- [ ] Medium
- [ ] Low

**Detectability:**
- [ ] High
- [ ] Medium
- [ ] Low
WE NEED YOU!
HOW YOU CAN CONTRIBUTE

PROJECT AT PROTOTYPE LEVEL

- DISCUSS USER REQUIREMENT
- RECEIVE PROPOSAL
- EVALUATE IDEAS
- OTHER..........
- MAYBE A TOPIC ON

RBM@PROMEDITEC.COM
QUESTION?

You are all invited at our demo desk

Luca Emili
luca.emili@promeditec.com