Pilot Project Description - Study Quality Management

Contents

1. Study Quality Management (SQM) Pilot Project ........................................................................ 2
2. Study Quality Management (SQM) Service ................................................................................ 3
3. Training .................................................................................................................................... 3
4. Abbreviations ............................................................................................................................ 5
1. Study Quality Management (SQM) Pilot Project

Clinerion encourages its clients to utilize a pilot project approach for the initial use of the Risk-based Study Quality Management service.

Pilot Project Activities

- Workshop on Application of Standard Risk-based Study Quality Management (SQM) Governance Guidelines
  - Presentation of and conclusion of a Standardized Risk-based SQM Model
  - Conclusion of a Pilot Project Plan
- Workshop on Setup of the Standard QRR Product: SQM
  - Introduction of the Quality Risk Radar (QRR)
  - Study, Risk Metric and User Input Configuration Specification
- Setup of Standard QRR Product: SQM
- Training of Pilot Project Team on Standard QRR Product: SQM
- Execution of the Pilot Project
- Pilot Project Support
  - Technical support if system issues arise
  - Ad hoc support if users need help
- Assessment of the Pilot Project Outcome
  - Meeting to discuss and interpret outcome
  - Improvements and lessons learned

Pilot Project Timeline

<table>
<thead>
<tr>
<th>Pilot Project Phases</th>
<th>Setup</th>
<th>Execution</th>
<th>Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Months</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Prepare and Conduct Workshops</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Setup QRR</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Train Pilot Project Team</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide Pilot Project Support</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Assess Pilot Project Outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pilot Project Restrictions

For SQM:
- Maximum of 3 studies
- Maximum of 2 risk assessments per study
- Maximum Pilot execution time of 3 months
2. Study Quality Management (SQM) Service

Risk-based Study Quality Management is supported by Clinerion with the standardized Study Quality Risk Assessment (SQRA) module which provides thorough risk assessments of the study protocol already before study start and also during the conduct of a clinical trial. The results identify risks to patient safety and/or data integrity arising from the protocol. By detecting those risks early and taking appropriate actions not only major issues are avoided, but also operational costs are lowered and resources can be directed to the critical areas. For example: the average time to study dossier submission is shortened by reducing the number of protocol amendments as the study protocol design team is notified of quality risks prior to protocol approval.

The Risk-based Study Quality Management service contains the following modules:
- The QRR Study Quality Risk Assessment (SQRA) module including a web-based questionnaire, risk calculation, risk reports
- the SQRA Risk Mitigation Tool with a set of root causes and mitigation actions, risk mitigation reports and the functionality to document results of root cause analyses and creation of risk management plans
- the QRR Data Upload Interface in which programs, studies, countries and users are added and maintained
- the QRR Configuration Module to enable an application configuration according to the client’s requirements

3. Training

To enable an efficient and effective preparation of the client’s pilot project team, Clinerion makes use of its standard training services.

- Quality Risk Management Introduction
- Study Quality Management Module

Clinerion provides these training sessions in the form of an Instructor Guide course.

Quality Risk Management Introduction Training:

Objective:

The objective is to introduce those affected by the QRM process to the principles of QRM and how they are applied to Clinical Operations in general and applied within the Quality Risk Radar in particular.

Included Topics:

- QRM Principles, Methodology, Calculation Model, Reporting, Risk Mitigation, Governance

Intended Audience: Those affected by the QRM process
Study Quality Management Training:

Objective:

The objective of this training is to provide a specific guidance on the Study Quality Risk Assessment (SQRA) process and how it is applied to Clinical Operations and within the Quality Risk Radar.

The training will give a step by step overview of all activities that need to be performed for setup and conduct of Study Quality Management by using the QRR including hands-on exercises and testing.

Included Topics:

- Set up of SQRA
- View your assigned tasks
- Access, complete and submit a SQRA questionnaire
- View, interpret and print SQRA reports
- Access, complete and submit mitigation tasks
- View, interpret and print risk mitigation reports

Intended Audience:

Users of QRR's Study Quality Management module, e.g. Study Managers, Data Management staff, Protocol Designers, etc.
4. Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DlaaS</td>
<td>Data Integration as a Service</td>
</tr>
<tr>
<td>KRI</td>
<td>Key Risk Indicator</td>
</tr>
<tr>
<td>QRR</td>
<td>Quality Risk Radar</td>
</tr>
<tr>
<td>RBM</td>
<td>Risk Based Monitoring</td>
</tr>
<tr>
<td>SQM</td>
<td>Study Quality Management</td>
</tr>
<tr>
<td>SQRA</td>
<td>Study Quality Risk Assessment</td>
</tr>
<tr>
<td>TSA</td>
<td>Trial Site risk Assessment</td>
</tr>
</tbody>
</table>