



EUROPEAN CENTRE FOR  
CLINICAL RESEARCH TRAINING

# **RISK BASED MONITORING**



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## 1 ECCRT Contact Details

### Contact details

#### **European Centre for Clinical Research Training (ECCRT)**

Cantersteen 47

1000 Brussels - Belgium

☎ +32(0)2 504 07 20

✉ [info@eccrt.com](mailto:info@eccrt.com)

🌐 [www.eccrt.com](http://www.eccrt.com)

## 2 Learning Objectives

Thank you for joining this course. We look forward to having you with us.  
After the course you will be able to:

- *Identify assess and response to risks associated with clinical projects*
- *Learn how to identify critical data*
- *Learn about technologies available to enable RBM*
- *Evaluate the risk indicator and set thresholds*
- *Identify the different actions needed linked to risk identification*
- *Learn how to implement this new concept within your organisation*

## 3 Agenda

<b>ELEARNING</b>	eLearning Duration: 1h 30 minutes (excluding quizzes and workshops)	
	<b><u>PART I – eLearning</u></b>	<b><u>Duration</u></b>
	Introduction	1 quiz + 1 workshop
	Rationale for RBM	09:00 min
	Risk Based Monitoring Methodology	05:30 min + 2 quizzes + 1 workshop
	Risk Assessment	16:00 min + 1 quiz + 1 workshop
	Critical Data and Risk Indicator	08:00min + 1 workshop
	Risk Plan	20:30 min + 1 quiz
	Monitoring Execution	20:30 min + 1 quiz + 2 workshops
<b>PART 1 (LIVE SESSION)</b>	<ol style="list-style-type: none"> <li>1. Concise review of the theory with Q&amp;A sessions* <ul style="list-style-type: none"> <li>● Workshops <ul style="list-style-type: none"> <li>- Risk identification and analysis</li> <li>- RACT</li> </ul> </li> </ul> </li> </ol>	

**PART 2 (LIVE  
SESSION)**

2. Risk Assessment Categorization Tool

- Workshop

1. RBM approach

- Workshop
  - Critical data and Risk indicator identification
  - Threshold Definition

2. Integrated Quality Risk Management Plan

3. RBM roles and responsibilities

4. RBM implementation

- Challenges and barriers
- RBM tools

5. Status on RBM implementation