

# Good Clinical Practice *In Practice*

Implementing ICH E6(R3)



**MRCT CENTER**

THE MULTI-REGIONAL  
CLINICAL TRIALS CENTER OF  
BRIGHAM AND WOMEN'S HOSPITAL  
AND HARVARD

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# The MRCT Center



The MRCT Center is focused on addressing the conduct, oversight, ethics, and regulatory environment of clinical trials.

## Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

## Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



 [www.mrctcenter.org](http://www.mrctcenter.org)

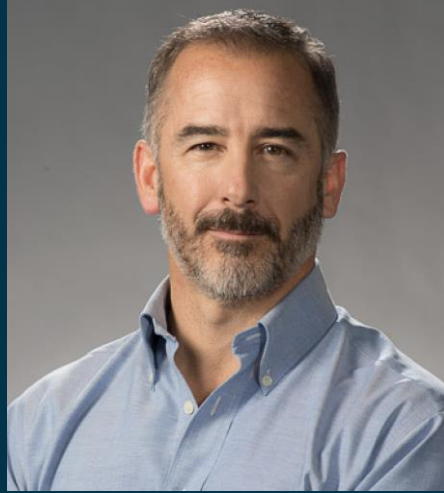
# Meet the Speakers



**Cheryl Grandinetti**

*Associate Director for Clinical Policy, Division of Clinical Compliance Evaluation, Office of Scientific Investigations, Office of Compliance, CDER, FDA*

FDA Topic Lead for ICH E6(R3)



**David Nickerson**

*Head of Clinical Quality Management, EMD Serono*

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*Consultant, RESaltas GmbH*

EFPIA Topic Lead for ICH E6(R3)

**Moderated by:**



**Sarah White, MPH**

Executive Director  
MRCT Center

# Today's Webinar:



The importance of implementing E6(R3) correctly

- Foundational Concepts
- Case Example: Applying the Concepts of Risk-Based Quality Management Principles
- Facilitated Discussion: Challenges in Implementation
- Q & A



# Foundational Concepts

## ICH E6(R3)

Annex 1

Annex 2

Principles of ICH GCP

# ICH E6(R3)

Annex 1

Annex 2

Appendix A

Appendix B

Appendix C

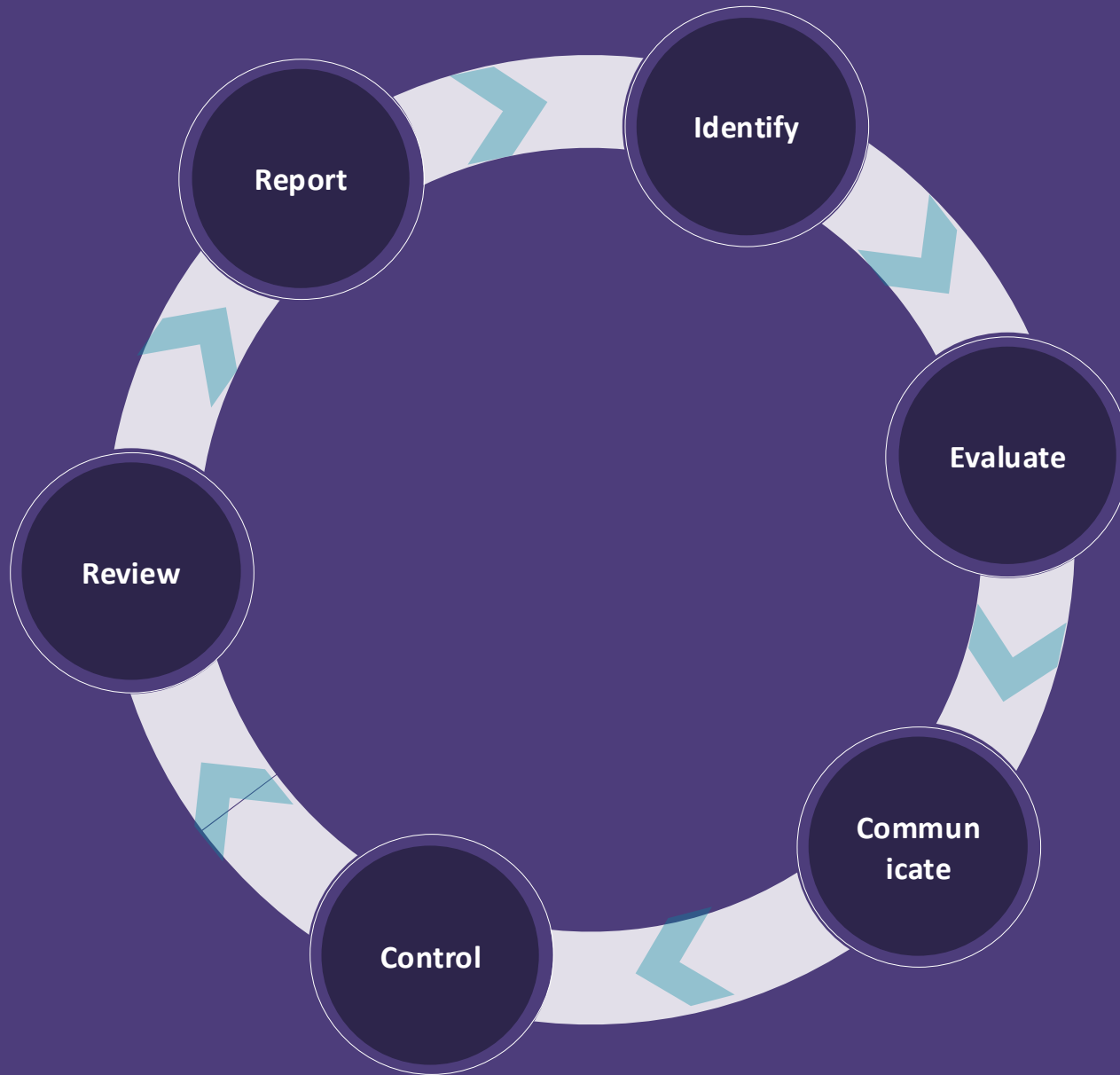
Glossary

Principles of ICH GCP

# Quality by Design

A **prospective** and **multidisciplinary** approach that focuses on:

- Gathering input from interested parties
- Identifying critical trial attributes  
**(Critical to Quality Factors)**
- Identifying, prioritising, and controlling important risks to trial attributes



# Quality Management

The design and implementation of efficient clinical trial protocols to ensure the rights, safety, and well-being of participants, and the reliability of trial results.

**Quality by Design**

**Quality Management**

Proactive activities  
**to identify and manage risks**  
associated with critical aspects  
of a clinical trial

# Fit for Purpose

Quality of the Clinical trial

- meets the trial's objectives
- provides confidence in the trial's results
- supports good decision-making

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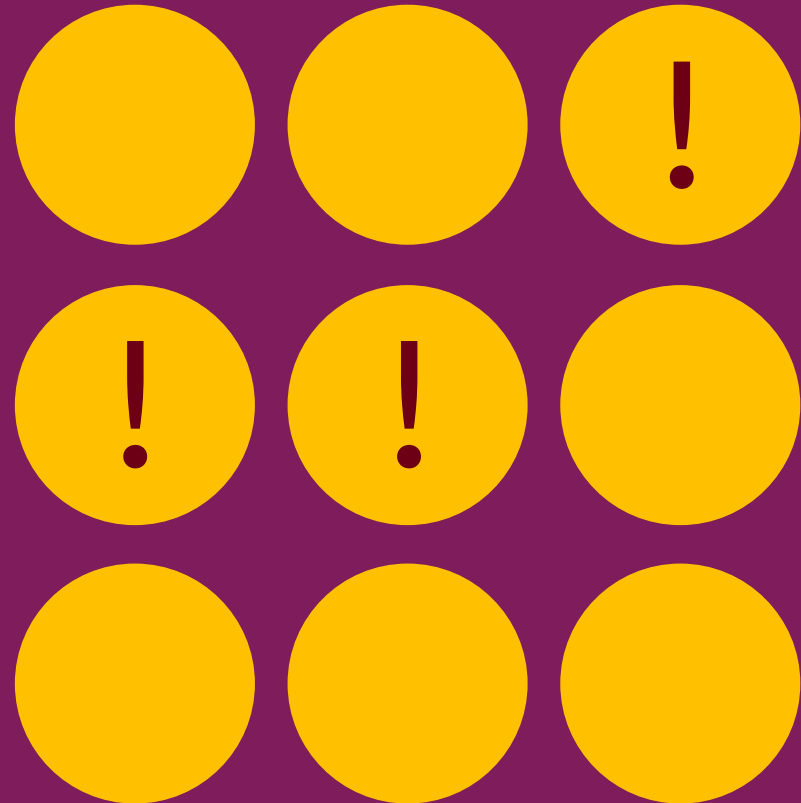
All while protecting the rights, safety, and wellbeing of  
trial participants



## Critical to Quality Factors

Attributes of a clinical trial whose integrity, if **compromised** due to inadequate design or poor conduct, could jeopardise **participant protection and the reliability of decision-making**.

- Can be data, processes, or systems
- Individualized to each individual clinical trial



## Risks

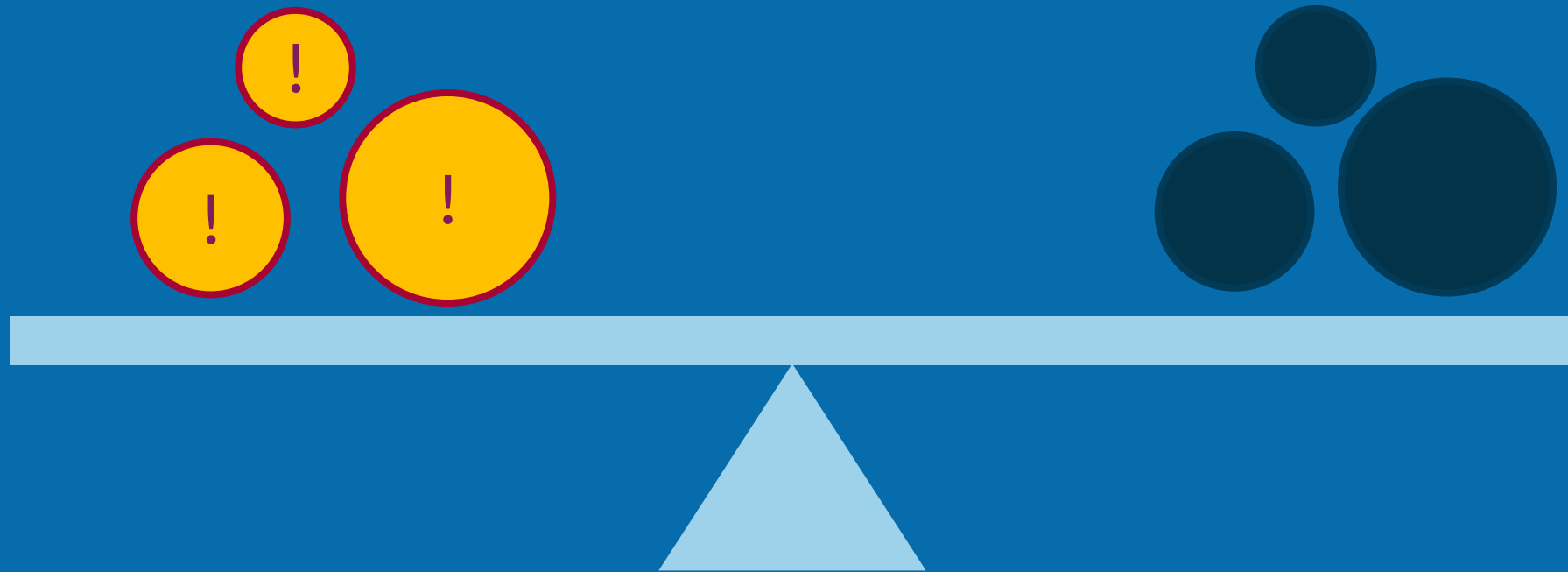
**The risks identified for each individual clinical trial will be different.**

Comprehensive understanding of the protocol, critical data, processes, and systems is needed



Risk proportionality is a core element of Quality by Design and Quality Management

# Proportionality





Case Example:

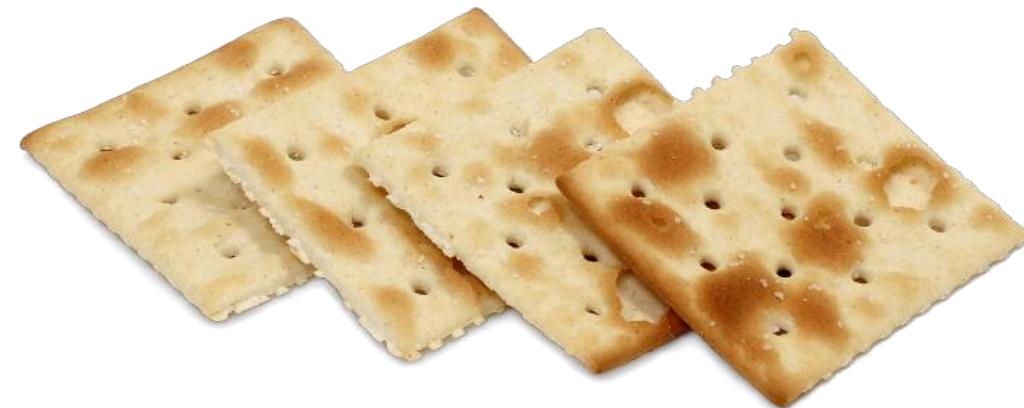
# Applying the Concepts of Quality by Design

# Critical to Quality Factors



	<b>Critical to Quality</b>	<b>Critical Data</b>	<b>Critical Process</b>
Crackers	Crackers are crispy and salty (but not too crispy or too salty)	<ul style="list-style-type: none"> <li>• Oven temperature</li> <li>• Baking time</li> <li>• Salt quantity</li> <li>• Crispiness index</li> </ul>	<ul style="list-style-type: none"> <li>• Baking process: Control baking temperature, surface, and time to achieve desired crunchiness</li> <li>• Process for adding salt (timing and amount)</li> <li>• Crispiness evaluation (QC process)</li> </ul>

<b>Not Critical to Quality</b>
<ul style="list-style-type: none"> <li>• Optional ingredients: Inclusion of sesame seeds or spices</li> <li>• Nutritional Content: Levels of vitamins or minerals that are not essential for the product's core quality (e.g., added fiber)</li> </ul>



# Risk-Based Quality Management



<b>Risks</b>	<b>Impact</b>	<b>Severity</b>	<b>Likelihood</b>	<b>Detectability</b>	<b>Mitigation</b>
Baking conditions are not per recipe	<ul style="list-style-type: none"> <li>Overcooked/undercooked</li> </ul>	<ul style="list-style-type: none"> <li>High</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>Pre-program ovens and cook cycles</li> </ul>
Salt quantities are not per recipe	<ul style="list-style-type: none"> <li>Flavor not desirable</li> </ul>	<ul style="list-style-type: none"> <li>High</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>Daily calibration of salting machine; use only qualified salt provider</li> </ul>
Baker performance does not meet expectations	<ul style="list-style-type: none"> <li>Inconsistent product</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>Med</li> </ul>	<ul style="list-style-type: none"> <li>Med</li> </ul>	<ul style="list-style-type: none"> <li>Baker training program; mentoring program</li> </ul>
Ingredients are not from usual providers	<ul style="list-style-type: none"> <li>Little known effect</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>High</li> </ul>	<ul style="list-style-type: none"> <li>None necessary</li> </ul>
Crisp parameters not achieved	<ul style="list-style-type: none"> <li>Consumer expectations not met</li> </ul>	<ul style="list-style-type: none"> <li>High</li> </ul>	<ul style="list-style-type: none"> <li>Low</li> </ul>	<ul style="list-style-type: none"> <li>High</li> </ul>	<ul style="list-style-type: none"> <li>QTL: &gt;99.1% of QC samples in acceptable range</li> </ul>

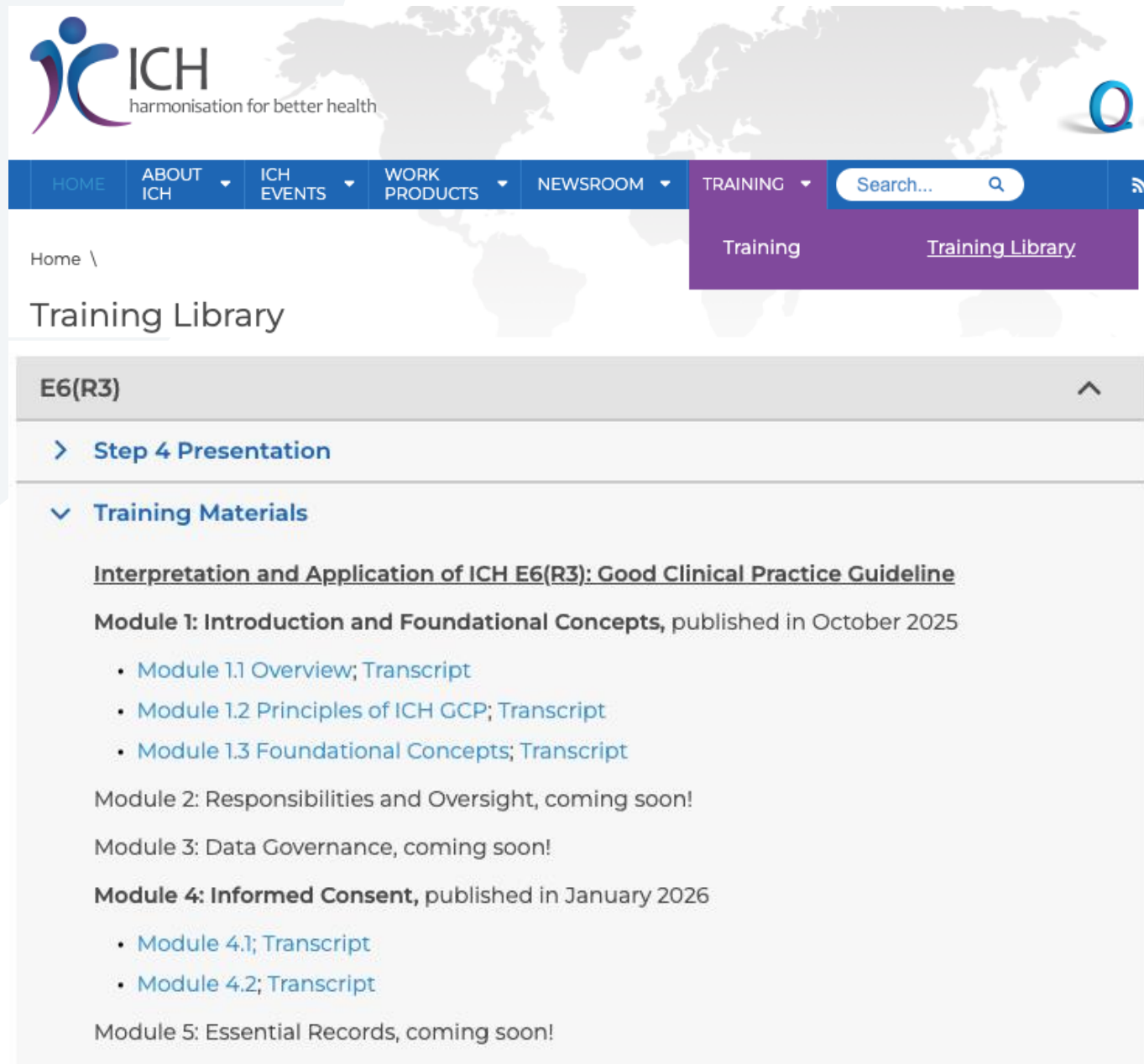


Facilitated Discussion:

# **E6(R3) in Practice & Challenges in Implementation**

# Official ICH E6(R3) Training Materials

[www.ich.org](http://www.ich.org)



The screenshot displays the ICH website's Training Library page. At the top, the ICH logo is accompanied by the tagline "harmonisation for better health". A navigation menu includes links for HOME, ABOUT ICH, ICH EVENTS, WORK PRODUCTS, NEWSROOM, and TRAINING. A search bar is located to the right of the menu. Below the navigation, a breadcrumb trail shows "Home \ Training Library". The main content area is titled "E6(R3)" and contains a list of training materials under the heading "Training Materials".

**E6(R3)**

> **Step 4 Presentation**

∨ **Training Materials**

**Interpretation and Application of ICH E6(R3): Good Clinical Practice Guideline**

**Module 1: Introduction and Foundational Concepts**, published in October 2025

- [Module 1.1 Overview; Transcript](#)
- [Module 1.2 Principles of ICH GCP; Transcript](#)
- [Module 1.3 Foundational Concepts; Transcript](#)

Module 2: Responsibilities and Oversight, coming soon!

Module 3: Data Governance, coming soon!

**Module 4: Informed Consent**, published in January 2026

- [Module 4.1; Transcript](#)
- [Module 4.2; Transcript](#)

Module 5: Essential Records, coming soon!





**THINK** + **DO**