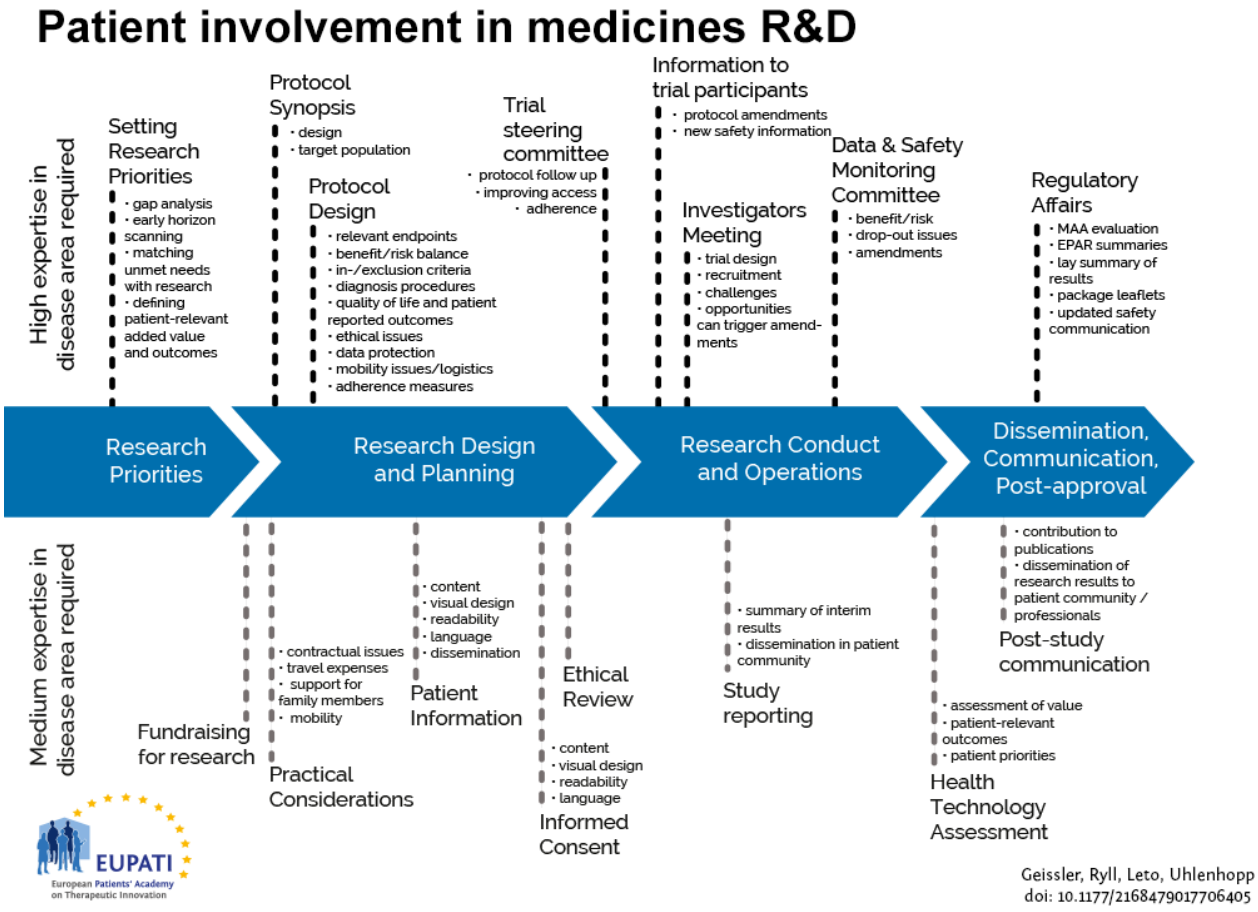
Mini-course starter kit- Data Monitoring Committees

Introduction

This EUPATI Mini-course starter kit is designed for patient involvement in data monitoring committees.

EUPATI Mini-course starter kits have been derived from content found in the EUPATI toolbox and EUPATI Patient Expert Training Course. The starter kits are thought to address roles that patients play in medicines development for example those shown in the figure below.



Patients can be involved across the process of medicines R&D. This diagram created by Geissler, Ryll, Leto, and

Uhlenhopp identifies some existing areas in which patients are involved in the process. It distinguishes between the level of expertise in a disease area that is required and the different areas where involvement can take place.

The starter kits provide you with links to relevant background reading in the toolbox and associated PowerPoint slide decks and media in order to prepare a single or multi-day training on the subject. Each of the starter kits contains a selection of PPT slides which you may use to educate patients/advocates about the “basics” in that area, e.g. in a two-hour to one-day seminar.

The starter kits are based on existing content from the EUPATI Toolbox, plus additional links to add-on Toolbox material. None of the “starter kits” are “ready-made course” modules – they are a ready-to-reuse resource for an experienced trainer to prepare and execute a course. You will need to edit them and put them into context.

Before you begin please download and review the ‘Manual for Trainers’.

- Presentation: Manual for Trainers
  Size: 722,143 bytes, Format: .pptx
  A manual for trainers describing how to use the EUPATI mini-course starter kits to create trainings on patient involvement.

Data Monitoring Committees

This starter kit provides background reading, slides, and quizzes to create training for patients who intend to become involved in data monitoring committees.

Core reading

Phases of clinical development

Basics of Early Clinical Development

Phase I Trials

Phase II Trials

Types of Study in Early Clinical Development

Within-trial decisions: Unblinding and termination

Clinical Trial Data Safety Monitoring Board (DSMB)

Data collection in clinical trials

Statistics in Clinical Trials - Key Concepts

Assessing the value of clinical trial results

Efficacy and safety of medicines

Critical reading of clinical study results

Epidemiology

Evidence based medicine

Optional

There is no optional content in the setting research priorities starter kit.

Presentations

Early clinical development [coming soon]

Data collection in clinical trials [coming soon]

- Within-Trial Decisions Unblinding and Termination

  Size: 375,386 bytes, Format: .pptx

  A presentation describing Within Trial Decisions, Unblinding (Code Breaking), Termination.

- Presentation: Statistics in Clinical Trials: Key Concepts

  Size: 381,778 bytes, Format: .pptx

  A presentation describing the key concepts of statistics in clinical trials, which can be adapted for own use.

- Assessing the Value of Clinical Trial Results

  Size: 367,550 bytes, Format: .pptx

  A presentation describing how to assess the value of clinical trial results, which can be adapted for own use.

- Presentation: Efficacy and Safety of Medicines

  Size: 373,525 bytes, Format: .pptx

  A presentation describing the efficacy and safety of medicines, which can be adapted for own use.

- Presentation: Critical Reading of Clinical Study Results

  Size: 399,949 bytes, Format: .pptx

  A presentation describing how to do a critical reading of clinical study results, which can be adapted for own use.

- Presentation: (Pharmaco)Epidemiology
  Size: 409,953 bytes, Format: .pptx
  A presentation describing epidemiology, which can be adapted for own use.

- Presentation: Evidence-based Medicine
  Size: 454,790 bytes, Format: .pptx
  A presentation describing evidence based medicine, which can be adapted for own use.

Quizzes

Quizzes will be provided for each presentation in the future on:

- Within-trial decisions
- Early clinical development
- Data collection in clinical trials
- Statistics in Clinical Trials - Key Concepts
- Assessing the value of clinical trial results
- Efficacy and safety of medicines
- Critical reading of clinical study results
- Epidemiology
- Evidence based medicine

Videos

An introduction to clinical research [ECRAN] can be downloaded from EUPATI on Youtube.

Explore the history of clinical trials stemming back to 1747 and learn more about how they work today in this short video from the ECRAN project.

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