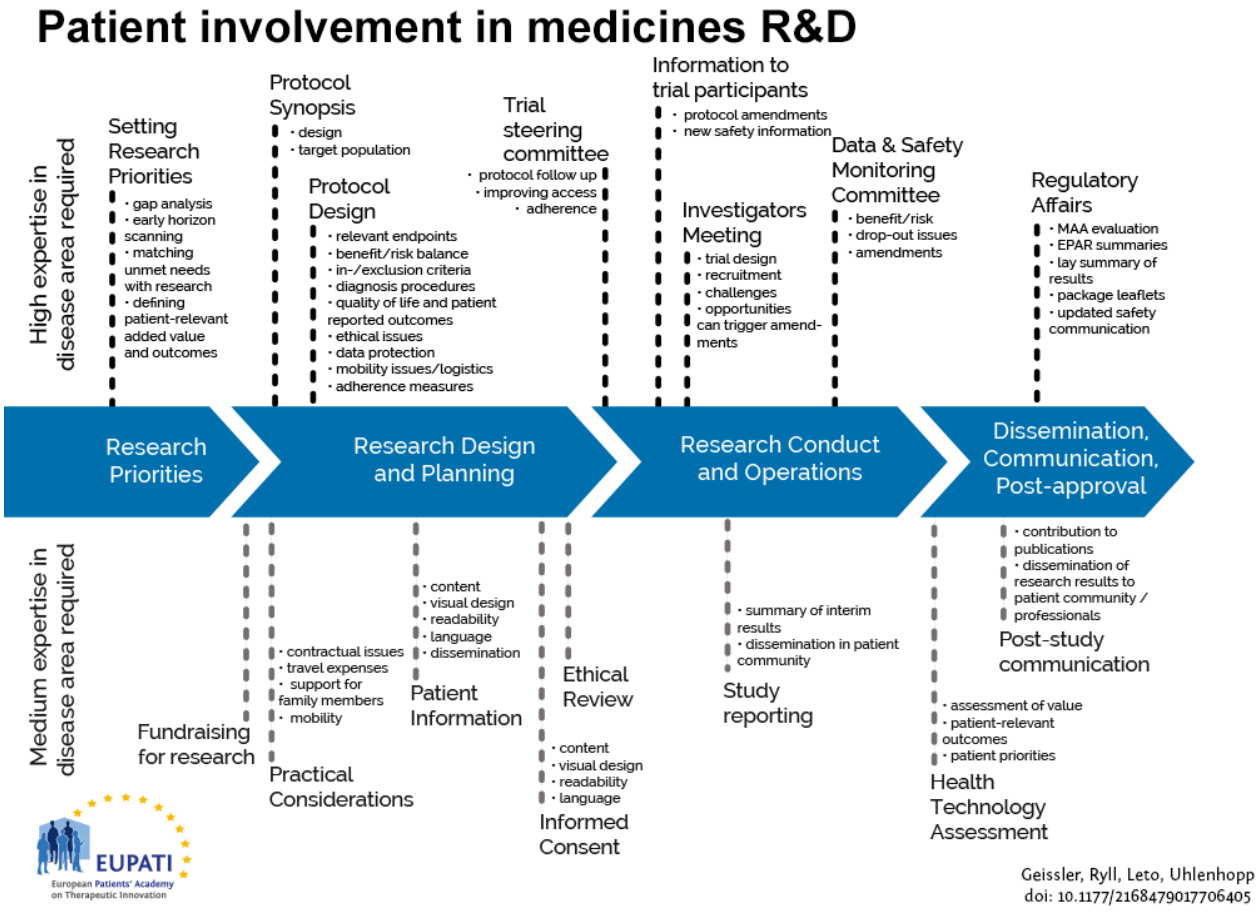
Mini-course Starter Kit – Protocol design

Introduction

This EUPATI Mini-course starter kit is designed for patient involvement in protocol design.

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**’: A manual for trainers describing how to use the EUPATI mini-course starter kits to create trainings on patient involvement.

[glossary_exclude]Protocol Design

This starter kit provides background reading, slides, a video, and quizzes to create training for patients who intend to become involved in protocol design.[/glossary_exclude]

[glossary_exclude]

Core reading

Making a medicine. Step 1: Pre-discovery

Making a medicine. Step 2: Target selection

Making a medicine. Step 3 and 4: Choosing a molecule or lead

Making a medicine. Step 5: Non-clinical safety testing

Making a medicine. Step 6: Phase I – Proof of mechanism

Making a medicine. Step 7: Phase II – Proof of concept

Making a medicine. Step 8: Confirmatory studies

Making a medicine. Step 9: Regulatory submission

Making a medicine. Step 10: Life-cycle management

New research areas in personalised medicines

Clinical Trial Designs

Evidence-based medicine

Role of statistics in clinical trials

The concept of blinding in clinical trials

Data collection in clinical trials

Optional

Clinical trials in small populations

Paediatric medicine: Paediatric Investigation Plan

Patient reported outcomes (PROs) assessment

Biomarkers

Basics of Early Clinical Development

Phase I Trials

Phase II Trials

Types of Study in Early Clinical Development

Presentations

Early clinical development (coming soon)

- Presentation: The basic principles of medicine discovery and development
  Size: 918,164 bytes, Format: .pptx
  The basic principles of medicine discovery and development. It takes over 12 years and over €1 billion to do all the research and development necessary before a new medicine is available for patients to use. This presentation details the process from discovery to release of a new medicine onto the market and beyond.

- Presentation: Clinical Trial Designs
  Size: 1,179,726 bytes, Format: .pptx
  A presentation covering the various types of clinical trial design. Details are given about blinding, control, comparisons, and randomisation.

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

- Presentation: The Role of Statistics in Clinical Trials
  Size: 354,126 bytes, Format: .pptx
  A presentation describing the role of statistics in

clinical trials, which can be adapted for own use.

- 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.

- Presentation: Blinding in Clinical Trials

  Size: 201,888 bytes, Format: .pptx

  This presentation provides more information about the concept of blinding in clinical trials.

- Presentation: Options for Data Collection and Patient-reported Outcomes (PROs)

  Size: 611,418 bytes, Format: .pptx

  A presentation covering the various types of data collection in clinical trials.

- Presentation: Ethical and Practical Challenges of Organising Clinical Trials in Small Populations.

  Size: 495,286 bytes, Format: .pptx

  A presentation detailing the ethical and practical challenges of organising clinical trials in small populations.

- Presentation: Paediatric Medicine: The Paediatric Investigation Plan

Size: 479,909 bytes, Format: .pptx
A presentation describing the Paediatric Plan, which can be adapted for own use.

- Presentation: Patient-Reported Outcomes (PROs) Assessment
  Size: 408,285 bytes, Format: .pptx
  A presentation describing the Patient-Reported Outcomes (PROs) Assessment process, which can be adapted for own use.

- Presentation: Biomarkers
  Size: 393,107 bytes, Format: .pptx
  A presentation describing biomarkers, which can be adapted for own use.

Additional Learning Resources

Are you ready to elevate your expertise with certifications in areas like Clinical Development, Medicine Discovery, and HTA Evaluation?

Explore the links below to access the EUPATI Open Classroom, choose the courses that match your interests, and embark on your learning adventure today!

- Learn more about the Steps of Making a Medicine!
- Explore Clinical Trials and delve in the Rights & Obligations of trial participants!
- What about Clinical Trials involving Special Populations? Don't Miss Out!
- Grasp key concepts of Statistical Methods used in Clinical Research!

- Deepen Your Understanding of Data Collection!
- Uncover the Practical Application and Vital Role of Patient-Reported Outcomes (PROs).
- Discover the Fundamentals of Early Clinical Development![/glossary_exclude]

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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