IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Practical Implementation of a Human Factors Study

5-6 November 2024
+ 4-5 March 2025, 1-2 July 2025, 18-19 November 2025

This training focuses on the practical and logistical aspects of planning, preparing and performing human factors studies for medical devices and combination products.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This training focuses on the practical and logistical aspects of planning, preparing and performing human factors studies for medical devices and combination products. We start at the planning stage, and cover all of the many challenges involved in preparing the study, running the interviews and dealing with the practical problems that can arise. We also include how to liaise with third parties such as the test venue staff, recruiters and of course the participants themselves.

The format of the training involves breakout sessions to practice the skills, and to share best practice.

Please note that this course is focused on human factors for **medical devices and combination products only**.

Benefits of attending

- **Learn** practical skills to conduct your next human factors study
- **Explore** how to stay legal during the study
- **Gain** solutions to common problems that occur during a study
- **Understand** data collection methods
- **Discuss** moderating skills

Who should attend?

This training would be relevant for human factors specialists who undertake formative and summative studies for medical devices and who want to develop their expertise to a higher level.

Programme

Day 1

Background to HF testing

- What are you trying to achieve in the test?
- What type of objectives should you set?
- What type of data are you trying to gather?
- Interviews or focus groups – which method is best?

Staying legal

- GDPR – how to design HF studies to comply with GDPR
- IRB / ethical approval – when you need it, and how to get it
- Sunshine act and HIPAA – rules for running the study in the US

Study preparation

- How to choose a test location
- How to schedule the participant interviews
- Monitoring progress – using a project planner
- Piloting – why you should run a pilot
- Incentives – setting a reasonable payment level

Study recruitment

- How to find a good recruiter
- How recruiters find participants
- How to help recruiters to get access to the right patient types
- How to work with the recruiter before, during and after the testing
- How to write a screener for a typical product test
- Common recruitment problems

Setting up the test interview

- Setting up the room - what to include
- How to lay out the test room
- Cameras – where to place them
- Where should the participant sit?
- Where should the moderator sit?

Day 2

Structuring the test interview

- How to welcome participants and put them at ease
- Checking participant identities
- Introduction – what to include in the introduction

Moderating the test interviews

- The role of the test moderator in formatives and in summatives
- How to construct a moderator's workbook
- How to work with the test observer / data analyst
- Children – how to include children and how to interview them

Moderating skills

- How to adopt the right mindset during the interview
- Listening skills
- Questioning skills
- Discussion skills for focus group moderators
- Empathy – how to achieve it and maintain it during the interview

Data collection

- Setting up the data set
- What types of data to include and exclude
- Full data set – what it is and how to create it during the testing
- Completing the paperwork – using the ALCOA method
- Quality control of the test outcomes – verifying and validating the data
- Adverse event reporting requirements
- How to deal with a faulty/broken device
- How to record protocol deviations

Common problems and how to deal with them

- Difficult / awkward / upset participants
- Noisy / interfering backroom staff
- Dealing with cancellations and last minute no-shows
- Dealing with late participants
- Participants who are very slow
- Injuries to participants (e.g. needlestick)
- Participants who fall ill during the test
- Participants with the wrong profile – what should you do?

Presenter

Richard Featherstone

Richard has 20 years of experience in planning and performing human factors studies in the UK, United States, Australia and Europe. He is able to blend a deep understanding of the technical human factors requirements for FDA and MDR, with the many logistical challenges of running a successful study. He has run over 150 HF studies for medical devices, combination products and diagnostic devices over a 20 year period. He is an experienced trainer too, and can communicate the many complexities of HF studies clearly and effectively.

Course dates

5-6 November 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15313*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 01 Oct**
4-5 March 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15314*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 28 Jan**
1-2 July 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15315*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 27 May**
18-19 November 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15316*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 14 Oct**

How to book

Online:
ipi.academy/2847

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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