Learning Outline

Client
Good Clinical Practice

Scope Details

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Client: Joe Bloggs

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Document Location

This document is only valid on the day it was printed.
The source of the document will be found in the Quality File.

Revision History

Date of next revision:

Revision date	Previous revision date	Summary of Changes	Changes marked
27/06/07		Initial Review LS	Tracked
10/07/07		Adjusted for new source material	Not tracked

Approvals

This document requires the following approvals.
Signed approval forms are filed in the project files.

Name	Signature	Title	Date of Issue	Version
Jocelyn Spence		Senior Instructional Designer		Final
Jocelyn Spence		Senior Instructional Designer		Final Rev2

Distribution

This document has been distributed to:

Name	Title	Date of Issue	Version
Joe Bloggs		27/06/07	Final
Jane Poggs		27/06/07	Final
Joe Bloggs		10/07/07	Final Rev2
Jane Poggs		10/07/07	Final Rev2

Learning Outline

Overview The Agency's Learning Outline document enables all project members to clearly understand the scope of development for the identified deliverable(s). It is a clear, concise and agreed-to description of the content to be covered and the treatment to be applied by the Instructional Design effort.

The document, by definition, also acts as an indicator to the whole team as to what will not be covered. Any requests for additional content post acceptance by the client will be subject to standard Agency management controls with regard to change control.

Intention It is the intention of this document to accurately describe:

- the aims and objectives of the stated deliverable(s)
- the approach the Agency Instructional Design team will apply to the approved content
- the main content headings that the deliverable(s) will contain
- the audience for whom the training will be prepared
- the duration of the course
- the use and treatment of audio (if relevant)
- the use and treatment of assessments (if relevant)
- any other relevant description of the content to be delivered

Learning Outline

Aim
The aim of this project is to deliver a maximum of 30 minutes of modular eLearning material covering the critical highlights of Good Clinical Practice for Client drug trials.

The eLearning modules will provide learners with practical, scenario-based guidance on how to conduct drug trials in accordance with Client's best practices. There will be a total of five self-study eLearning modules within the program.

The eLearning will be interactive, using questioning techniques throughout to stimulate the learner and encourage thinking and engagement.

Objectives
Upon completing the eLearning, the learner will be able to:

- understand Client expectations of Investigators for a clinical trial
- understand what is meant by Good Clinical Practice (GCP)
- understand his or her responsibilities as an Investigator
- be able to carry out his or her responsibilities for the study

Approach
The content of the eLearning will address Investigators' responsibilities and the reasons behind the guidelines and regulations they are being asked to follow. The material will present only the highlights of the GCP guidelines, focusing on the knowledge and understanding that Investigators will need in the day-to-day exercise of their duties. Users will be asked to make judgements to increase awareness of the positive or negative effects of their choices on eventual outcomes. Emphasis will be placed on treating users as competent, valuable members of the Client community.

Topics
The following table describes the topics that the eLearning will use based on the original PowerPoint and where in the course each topic will be handled. Please note that this is a rough estimation based on the original PowerPoint, and that content from individual slides may appear elsewhere in the final course.

Learning Outline

	Module 1	Module 2	Module 3	Module 4
Slide 3, expectations	x			
Slide 5, definition and value of GCP Slides 9-11, history (to be presented as downloadable extra)	x			
Slide 6, how Client complies with GCP (Standards of Data) Slide 7, consequences of non-compliance			x	
Slide 8, common FDA GCP inspection findings	x			
Slide 12, contents of ICH guideline (Standards of Data)			x	
(2) (3) (4) Slide 14, investigator's qualifications and agreements*		x	x	x
(2) Slide 15, adequate involvement in the trial*		x		
(3) Slides 16 & 20, compliance with protocol*			x	
(4) (3) Slides 17-18, communication with IRB/IEC*		x	x	x
(6) Slides 19 - 20, investigational product accountability*			x	
Slide 20, responsibilities on subject information and randomisation procedures* (Safety of Subjects)		x	x	
(4) Slides 21-22, IP record keeping*				x
Slides 23 & 20, destroying IP* (Standards of Data)			x	
(1) Slide 24, informed consent (key)*			x	
(4) Slide 25, safety reporting of adverse events*				x
(4) Slide 26, purpose of source documentation* (see next)				x
(4) Slides 27-30, recommended contents of source documents, source data (see previous and next)				x
(4) Slide 31, CRF as a source document (see previous and next)				x
(4) Slides 32-34, source documentation verification (see previous and next)				x
(4) Slide 35, electronic subject records (see previous)				x

(4) Slide 36, electronic source documentation				x
(4) Slides 38-42, essential documents for the conduct of the clinical trial, ICH section 8, before during and after the trial				x

*high-level responsibility

Main Content
The eLearning will include the following modules, though the content will not necessarily be structured in this way:

1. **Module 1: Why GCP?**
    a. Course Objectives
    b. How to use this course
    c. What's in it for me?
        i. Definition of GCP – Slide 5
        ii. How Client complies – Slide 6-7
        iii. You're the link between the test subjects and those who might benefit from the drug in the future
    d. Common findings – Slide 8
    e. Expectations – Slide 3

2. **Module 2: Safety of Subjects**
    a. Safety of Subjects scenario
    b. Adequate investigator site facilities/training of staff
        i. Slide 14
        ii. Slide 15
        iii. Slide 20 if not in 2b
    c. Ethics committee
        i. Slide 17-18

3. **Module 3: Standards of Data**
    a. Standards of Data scenario
    b. Informed consent
        i. Slide 5
        ii. Slide 12
        iii. Slide 24
    c. Monitoring
        i. Slide 14
        ii. Slide 16
        iii. Slide 17-18
        iv. Slide 20
    d. Drug accountability
        i. Slide 19-20
        ii. Slide 23

4. **Module 4: Documentation**
    a. Documentation scenario
    b. Documentation

i. Slide 14
ii. Slide 17-18
iii. Slide 21-22
iv. Slide 25-42

5. **Module 5: Quiz**
    a. Quiz
    b. Recap
    c. Mark complete

Audience
The target audience includes all doctors and nurses involved in drug trials for Client on sites around the globe. The course will use international English with UK spellings and will use visuals as much as possible.

Duration
The total combined duration of the eLearning modules will be no longer than 30 minutes.

Audio
The eLearning will include appropriate audio throughout where narrative text is used.

Design
The modules will include elements from the following multimedia types:

- Animation
- Graphics
- Audio
- Simulations
- Instructional text

Additional Elements for Inclusion:

- Key Facts – hints and tips
- Post lesson/module assessments/questioning techniques
- Knowledge Check assessment mechanism
- Bookmarking (enabling the learner to resume the course where s/he left off)
- Module progress indicators

Scoring
The Learning Management System will record enrolment, unenrolment and completion. The course will include a quiz in the final module. Users must complete the quiz in order to mark the course as complete, but they will not be required to achieve a particular score or percentage. All questions will present feedback for correct and incorrect answers to give users reinforcement on correct responses and best practice. Once users have entered or completed the course, they will be able to access the quiz directly from the main menu without stepping through the information and activities in the other sections (modules).