

**SKILLS FOR MONITORING NON-COMMERCIAL CLINICAL TRIALS  
AGENDA DAY ONE**

<b>0900 - 0920</b>	<b>REGISTRATION</b>
<b>0920 - 0935</b> <b>15mins</b>	<b>Introduction</b>
<b>0935 - 1035</b> <b>1hr</b>	<b>Purpose and Scope of Monitoring</b> <ul style="list-style-type: none"> <li>• Define the purpose and scope of monitoring</li> <li>• Identify the factors to consider for evaluating risk</li> <li>• Describe the benefits of monitoring</li> <li>• Distinguish the types of monitoring</li> </ul>
<b>1035 - 1120</b> <b>45mins</b>	<b>Overview of Drug Development</b> <ul style="list-style-type: none"> <li>• Explain why clinical trials/studies are undertaken</li> <li>• Describe the main phases of drug development</li> <li>• Understand how the phases of drug development and study designs effect the monitoring plan</li> </ul>
<b>1120 - 1140</b>	<b>BREAK</b>
<b>1140 - 1240</b> <b>1hr</b>	<b>Overview of Monitoring During the Life Cycle of a Research Study</b> <ul style="list-style-type: none"> <li>• Explain the life cycle of a study in terms of: <ul style="list-style-type: none"> <li>– Start up process including required approvals, study progression to study end</li> </ul> </li> <li>• Define the importance of an initiation visit</li> <li>• List the tasks involved in a monitoring visit during the study and at study close out</li> </ul>
<b>1240 - 1340</b>	<b>LUNCH</b>
<b>1340 - 1455</b> <b>1hr 15mins</b>	<b>Monitoring Adherence to the Principles of Good Clinical Practice &amp; UK Regulations</b> <ul style="list-style-type: none"> <li>• Describe what is involved monitoring adherence to the principles of Good Clinical Practice and UK regulations on clinical research</li> <li>• Discuss the sponsor &amp; investigator responsibilities</li> <li>• Recognise the important responsibilities of the monitor</li> </ul>
<b>1455 - 1515</b>	<b>BREAK</b>
<b>1515 - 1645</b> <b>1hr 30mins</b>	<b>Introduction to Monitoring Skills</b> <ul style="list-style-type: none"> <li>• Identify the tasks required before a monitoring visit and rank their contribution to its success.</li> <li>• Critically evaluate the role in trial management of the Essential Documents, required by GCP regulations, and held in the site trial file</li> <li>• Assess site performance in relation to protocol adherence, sponsor SOPs and applicable UK regulations</li> <li>• Identify the key variables in a trial protocol and describe the steps needed to verify these in accordance with sponsor SOPs and applicable UK regulations</li> </ul>
<b>1645 - 1700</b> <b>15mins</b>	<b>Discussion of overnight reading material &amp; any further questions</b> <b>End of Day one</b>

**AGENDA - DAY TWO**

<b>0900 - 0910</b>	<b>REGISTRATION</b>
<b>0910 – 1040 1hr 30mins</b>	<b>Introduction to Monitoring Skills Day 2</b> <ul style="list-style-type: none"> <li>• Recognise and accurately report any deviations with the recruitment &amp; consent processes and verify only eligible subjects are enrolled</li> <li>• Establish if pharmacy and laboratories are fit for purpose</li> <li>• Analyse findings and decide follow up actions</li> </ul>
<b>1040 - 1100</b>	<b>BREAK</b>
<b>1100 – 1200 1hr</b>	<b>Monitoring Skills continued</b> (from above)
<b>1200 - 1300 1hr</b>	<b>Monitoring practice - WORKSHOP</b>
<b>1300 - 1400</b>	<b>LUNCH</b>
<b>1400 – 1500 1hr</b>	<b>Workshop feedback session</b>
<b>1500 - 1600 1hr</b>	<b>Monitoring Report and Follow Up Actions</b> <ul style="list-style-type: none"> <li>• Record accurately the monitoring visit into a monitoring visit report</li> <li>• Identify the actions to follow up and define the steps to initiate corrective actions</li> <li>• Construct a follow up letter</li> <li>• Recognise when to escalate problems within approved procedures</li> </ul>
<b>1600 - 1620</b>	<b>BREAK</b>
<b>1620 - 1650 30mins</b>	<b>Competencies for Monitoring</b> <ul style="list-style-type: none"> <li>• Define at least 5 competencies of effective monitors</li> <li>• Assess their current level of competence as a monitor</li> <li>• Develop a plan of action to improve their work as a monitor</li> </ul>
<b>1650 - 1700 10mins</b>	<b>Evaluations and Close of Session</b>