K7 Vendor Oversight in Clinical Trials

12th May 2021

The day will start at 08:45 with registration and coffee for a prompt start at 09:15. We aim to finish by 17:30.

ICR Training

K7 Vendor Oversight in Clinical Trials

10 CPD POINTS

12th May 2021

K7

Venue - Online Course,

Course Information

The Course

This course will run ONLINE VIA ZOOM. Vendor Oversight is currently a hot topic as sponsors and vendors aim to get to grips with what is really required. You don't want to outsource and then expend multiple resources to manage and oversee your trial. As a vendor you want to get on with the outsourced clinical trial in the most effective way feasible without micromanagement from your sponsor company. What is required to compliantly and efficiently implement vendor oversight? What are the risks and challenges of not getting this right from the beginning? This course will aim to work through some of these challenging topics with time given to work through specific scenarios from the attendees.

Learning Objectives

• Understand the regulatory expectations that impact Vendor management and Vendor Oversight including any up-coming revisions
• Understand different Outsourcing Models and what they mean when implementing effective Vendor management and Oversight.
• Understand the requirements for selecting vendors to meet your outsourcing requirements
• Understand expectations for Vendor Oversight and how to implement a practical vendor oversight plan.
• Be aware of all of the components of vendor governances and understand what is right for your organization

• Understand what makes excellent vendor management and oversight to support excellent delivery

Course Outline

• Meeting Regulatory Expectations: recent industry and regulatory items that impact Vendor Oversight to include proposed ICH E 6 revisions.
• Understanding different outsourcing models: what could work best for your organization
• Getting off on the right foot: Selecting the right providers for your outsourcing model
• Vendor Oversight: what are the key components of Vendor oversight
• Implementing an effective Governance Structure
• Implementing Vendor Oversight to gain effective project delivery

• Q&A on Vendor oversight and specific requirements

Who would benefit

Clinical Researchers involved in Vendor Management and Oversight of clinical trials, from both sponsors & suppliers for example: Project Managers, Outsourcing managers, Clinical Operations, Clinical Data Management, Medical Writing.

Course Fees

Guest	**£550.00**
ICR Member	**£450.00**
ICR Member Academic	**£350.00**

Your Trainer

Julianne Hull

With over 25 years' experience in clinical development Julianne has successfully held global leadership roles in vendor management/outsourcing and clinical operations for several large and medium pharmaceutical companies (Pfizer, Wyeth, Marion Merrell Dow, Biogen Idec and Ipsen). In these roles, she has been an accomplished manager and motivator of staff based in China, India, Japan, Europe and US.

Within Wyeth Julianne developed, implemented and ran the key cross functional governance body to drive successful delivery for inspection ready clinical trials. Responsible for the strategic development and implementation of unique, quality and cost-effective methods of outsourcing Clinical Data Management led to the establishment of the ground-breaking Wyeth Accenture strategic alliance in 2003. Julianne had business and operational oversight of the Wyeth/Accenture alliance through the acquisition of Wyeth by Pfizer in 2010. For Wyeth, Biogen Idec and Ipsen Julianne had critical roles in the development and implementation of effective service provider governance.

Pre-Course Questionnaire - To be completed by all delegates

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Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Course Title: K7 Vendor Oversight in Clinical Trials

Date: 12 May 2021

Name: .....

Company / Hospital: .....

Position / Job Title: .....

How much experience of clinical do you have? (Years)

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What are you hoping to get out of the day?

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State one issue/problem you would like discussed at the meeting

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Dietary Requirements

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* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.

Training Location

Address: Online Course,

This course/forum will run online via Zoom

Local Taxi Companies

N/A

Accommodation

The ICR does not specifically recommend any accommodation - however the following are within easy travelling distance of the training venue

There are also a number of travel websites which may allow you to identify local accommodation and special offers - e.g. expedia

The Small Print

As a matter of policy we do not issue electronic copies of the slides used.

All ICR materials are copyrighted.

All delegates receive a delegate book.

Payment must be received in advance of a training course commencing. The ICR has the right to refuse entry for non-payment. Payment by invoice must be settled within 14 days from the date of invoice.

We understand that occasionally circumstances may change and that you will be unable to attend your chosen course. Notification of cancellation must be made in writing. If you cancel **more than 14 days prior to the event**, we will refund the course less £50 to cover administration costs. If you cancel within 14 days, no refund will be payable, but we will allow you to transfer to another course of your choice.

We will accept a change of delegate at any time without you incurring a penalty. The Institute of Clinical Research reserves the right to cancel any course that is under-subscribed but will give you 7 days notice in writing and will refund your course fees without any liability for any consequential or indirect loss.

At anytime, you may transfer to the same course within 12 months, or to another course of your choice within 6 months; a £25 administration fee will be charged for such transfers.

We may also need to change the venue but will give you 7 days notice in writing of the new location.

Programmes as published are correct, however due to circumstances beyond our control, trainers, speakers and/or the programme may need to be altered occasionally.

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Registration Form

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Registration Form

Please photocopy this form for further registrations

Course Title: K7 Vendor Oversight in Clinical Trials **Course Date:** 12 May 2021

Membership No.: ..... **Title(Dr,Mr,Mrs,etc):** ..... **First Name:** .....

Surname: ..... **Job Title:** .....

Company Name: .....

Email Address: .....

Confirmation of booking will be sent by email, unless you request here that it is sent by post ☐

Correspondence Address

Address: .....

Postcode: ..... **Country:** ..... **Telephone Number:** .....

Special Dietary Requirements

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Declaration

I agree to the terms and conditions of booking **Signature:** .....

Method of Payment

Please not that your place will only be confirmed when payment has been received (please tick as required)

I wish to pay the fee of .....

☐ I enclose a cheque payable to "The Institute of Clinical Research"

OR

☐ I wish to pay by

☐ VISA ☐ MASTERCARD ☐ DELTA ☐ EUROCARD

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Start Date ☐☐ ☐☐ **Expiry Date** ☐☐ ☐☐

Name (as it appears on the card) .....

Signature of card holder .....

OR

☐ Please invoice my company using Purchase Order Number ☐ Invoices can only be raised when a PO no. is provided

Correspondence Address

Address: .....

Postcode: ..... **Country:** .....