

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

Assessment and Medical Evaluation of Individual Case Safety Reports

Hybrid event: Novotel London West Hotel, London and Online

18 - 19 October 2023

Wednesday 18 October

0830 - 0845
(BST)

Registration

0845 - 0900

Introduction to the course

0900 - 0930

Regulatory requirements for ICSRs, principles/definitions

0930 - 0935

Comfort break

0935 - 1050

Medical review, company causality and seriousness assessments
(Including practical session)

◇ Spontaneous, Other solicited sources (Compassionate use and NISs) and Interventional studies

1050 - 1100

Comfort break

1100 - 1215

Special Situations

1215 - 1220

Comfort break

1220 - 1300

Special Situations practical session

1300 - 1400

Lunch

1400 - 1430

Introductory webinar

1430 - 1440

Comfort break

Book your place here: <https://www.dsru.org/education-training/>
Contact us on EandT@dsru.org or 023 8040 8600

Prog draft 1 WEB (ICSR 23)
In the event of unforeseen circumstances, the DSRU
reserves the right to alter the programme, speakers or venue.

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1440 - 1525 MedDRA coding

◇The importance of coding, principles of coding, types of data for coding, specific challenges and practical exercises

1525 - 1530 Comfort break

1530 - 1630 Practical session on MedDRA coding

1630 End of day one

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Registration

0845

Start of day 2

0845 - 0930

Management and training of third party suppliers

0930 - 0935

Comfort break

0935 - 1020

Literature and cluster reports

1020 - 1030

Comfort break

1030 - 1130

Practical session on literature and cluster reports

1130 - 1135

Comfort break

1135 - 1220

Company Clinical Comments and Periodic Report comments

1220 - 1225

Comfort break

1225 - 1325

Practical session on narrative writing, company and periodic report comments

1325 - 1415

Lunch break

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1415 - 1515 **Regulatory reporting and electronic submissions**

1515 - 1520 **Comfort break**

1520 - 1605 **Quality reports from regulatory authorities**

1605 - 1615 **Comfort break**

1615 - 1715 **Practical session on quality reports**

1715 **Close of meeting**

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