

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

Back to Basics in Pharmacovigilance

Online training

22 - 23 February 2023

Wednesday 22 February

0815 – 0845 (GMT)	Registration
0845 - 0900	Introduction to the meeting
0900 - 0945	Definitions, History, Classifications of ADRs, Basic Principles of Pharmacovigilance [DSS 1, 3] <i>◇ Definition of pharmacovigilance ◇ History of pharmacovigilance ◇ Operational definitions (serious, non-serious, expected, unexpected) ◇ Classification of ADRs ◇ Basic causality assessment ◇ Characteristics of different systems of reporting ◇ Strengths ◇ Weaknesses ◇ Definitions Medication errors, off-label, overdose, misuse</i> Learning objectives: <ul style="list-style-type: none">• To revise founding principles of pharmacovigilance• To become familiar with current ICH and regulatory basic definitions and be aware of change during interpretation both in the EU and USA• To understand simple causality assessment, the principles behind current spontaneous reporting systems, and the logic behind pharmacovigilance planning (ICHE2E)
0945 - 0950	Comfort break
0950 - 1030	Definitions, History, Classifications of ADRs, Basic Principles of Pharmacovigilance continued
1030 - 1040	Comfort break
1040 - 1120	Ethics and transparency in pharmacovigilance [DSS 1] Learning objectives: <ul style="list-style-type: none">• For you to consider relevant ethical principles from an individual and societal point of view and outline the available ethical safeguards• To provide you with an understanding of main issues relating to transparency in pharmacovigilance i.e., availability of data and information about processes, and conflicts of interest
1120 - 1130	Comfort break
1130 - 1140	Introduction to interactive session: History of Pharmacovigilance
1140 - 1300	Interactive session: History of Pharmacovigilance <i>◇ Case study: SSRIs / Coxibs</i>

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

Prog draft 3 WEB (B2B Feb 23)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

1300 - 1345 Lunch

1345 - 1445 Interactive introduction to international collaboration in pharmacovigilance [DSS 1,2, 3, 4, 8]

◇ Review of the structure of ICH and how guidelines are developed (ICHE2BM, ICH E2C (PSURs/PBRERs), ICHE6 (GCP), ICHE3 (reporting standards)) ◇ CIOMS – outlines of: I, II and V (spontaneous reporting, CCSI, DCSI); IV (risk benefit assessment) and VI (clinical trials) ◇ Aggregate reports PSURs/PBRERs/DSURs ◇ PILs

Learning objectives:

- Gain an understanding of the need for global pharmacovigilance and in particular for standardisation of collection and monitoring of data and the principles of risk benefit analysis

1445 - 1455 Comfort break

1455 - 1540 Interactive introduction to international collaboration in pharmacovigilance [DSS 1,2, 3, 4, 8] continued

1540 - 1550 Comfort break

1550 - 1650 Digital and social media for pharmacovigilance

Learning objectives:

- To review regulations and guidelines for pharmacovigilance associated with digital media
- To develop an understanding of the landscape of social media including the key concepts of pharmacovigilance and social media, focusing on company-sponsored activities, and including patient-centred sites
- To assess the content of social media as a source of individual case safety reports
- To understand the potential for signal detection using aggregated data from digital media sources
- To receive an introduction to the Web-RA_{DR} IMI project including an assessment of the capabilities of social media for pharmacovigilance and benefit risk reporting by patients
- To consider how digital media will impact the current operating model for pharmacovigilance

1650 Close of day one

1655 - 1745 PMST trainees and Postgraduate Students ONLY are requested to meet the Assessors to discuss their pre-course assignment for this course

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

Prog draft 3 WEB (B2B Feb 23)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

Back to Basics in Pharmacovigilance

Online training

22 - 23 February 2023

Thursday 23 February

0830 – 0845 (GMT)	Registration
0845	Start of day 2
0845 - 0930	Regulatory aspects of pharmacovigilance – post-marketing [DSS 1, 2, 3, 4] <i>◇ Legal basis of pharmacovigilance ◇ Roles of MHRA, CHM, EMA, CHMP, PRAC ◇ Relevant Guidelines</i> Learning objectives: <ul style="list-style-type: none">• To understand the legal principles of pharmacovigilance and the enactment of European legislation directly for pharmaceuticals
0930 - 0935	Comfort break
0935 - 1020	Regulatory aspects of pharmacovigilance – post-marketing continued [DSS 1, 2, 3, 4]
1020 - 1025	Comfort break
1025 - 1125	Regulatory aspects of pharmacovigilance – premarketing [DSS 1, 2, 3, 4] <i>◇ New clinical trial regulation ◇ Clinical trials Directive ◇ FDA (roles and responsibilities of therapeutic diagnoses, epidemiology group, Medwatch and AERS) ◇ FDA guidelines, points to consider and PDUFA III</i> Learning objectives: <p>To provide you with an understanding of the legal principles of pharmacovigilance through the enactment of EU and US legislation directly for pharmaceuticals</p>
1125 - 1135	Comfort break
1135 - 1240	Current practical pre-marketing Drug Safety [DSS 1, 2, 4] <i>◇ ADR reporting rules ◇ Clinical trials directive requirements ◇ US PDUFA III aspects of safety monitoring ◇ High mortality clinical trials ◇ DSMBs ◇ DCSIs and the concept of expectedness</i> Learning objectives: <ul style="list-style-type: none">• To familiarise yourself with the differences of pharmacovigilance reporting in clinical trials and especially pre-registration
1240 - 1325	Lunch
1325 - 1415	Pre-marketing safety monitoring and evaluation [DSS 1, 2, 3, 4] <i>◇ Principles of risk benefit safety assessment within a clinical development plan ◇ Preclinical</i>

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

Prog draft 3 WEB (B2B Feb 23)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

safety assessment ◇ *Phase I* ◇ *Phase II* ◇ *Phase III*

Learning objectives:

- To achieve an understanding of the approach to developing the safety data base on which the risk benefit evaluation of a new medicinal product will be based

1415 - 1420 **Comfort break**

1420 - 1525 **Interactive session: Reporting adverse drug reactions**

1525 - 1530 **Comfort break**

1530 – 1600 **Practical aspects of signal detection [DSS 1, 3]**

◇ *Handling of signals in Pharmaceutical Companies* ◇ *Pre-licensing vs post-licensing issues*
◇ *Systems and software for detecting signals* ◇ *Regulatory interactions* ◇ *Interface between signals and risk-management strategies* ◇ *Coding systems for drug safety*

Learning objectives:

- To understand how pharmaceutical companies approach signal detection and management, and the resources available to them

1600 - 1610 **Comfort break**

1610 - 1715 **Impact of adverse drug reactions [DSS 8]**

◇ *Informed consent* ◇ *PILs, provision of information* ◇ *When things go wrong* ◇ *Consumer groups*

Learning objectives:

- To understand how patients, carers and the public understand risk benefit and perceive pharmacovigilance. To illustrate pharmaceutical obligations.

Followed by;

New developments in pharmacovigilance [DSS 1, 3, 4, 8]

◇ *ICHE2E and Risk management planning* ◇ *Future directions* ◇ *Safety aspects of advanced therapies*

Learning objectives:

- To discuss new methods for detection and prioritisation of signals derived from spontaneous ADR reports

1715 **Close of meeting**

1715 - 1730 **Postgraduate in Pharmacovigilance students and PMSTs only**
Student meeting to discuss any questions regarding the post-course assignment

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

Prog draft 3 WEB (B2B Feb 23)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org