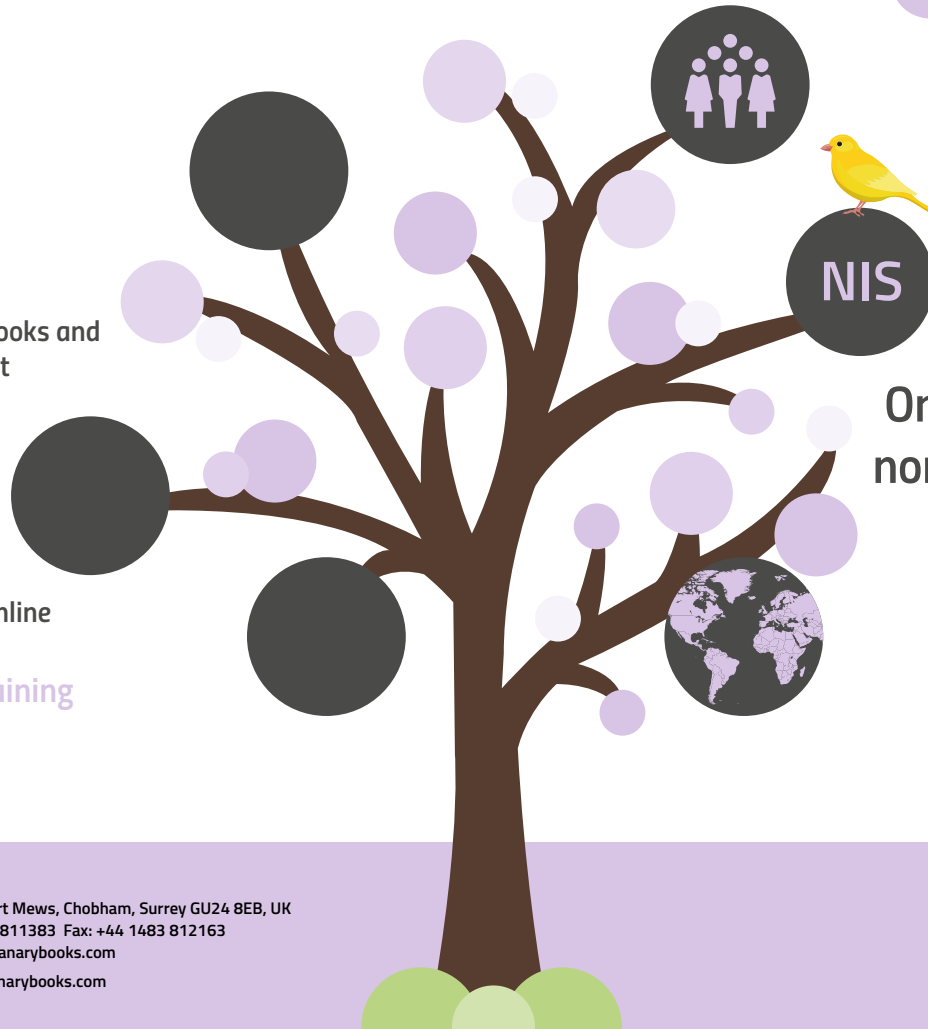


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- Why perform NIS?
- Definition of NIS
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- Data protection
- Requests by regulators
- PAS, PASS, PAES explained
- NIS in pharmacovigilance
- Pharmacovigilance inspections
- Abbreviations explained
- Glossary of terms, abbreviations
- Short quiz

NIS, Practical Aspects (Module 2)



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- Choosing a design
- Role of SCOPE, GRACE principles
- Cross-sectional, case-control and cohort studies
- Protocol content and development
- Declaration of Helsinki and NIS
- ENCePP guidance
- Study milestones
- Consent in NIS
- Study conduct
- Analysis of data
- Codes of conduct, agreements
- Scientific independence
- Monitoring
- MAH oversight obligations
- NIS and safety reports, risk management plans
- Data privacy
- Study report
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- Documentation and archives
- Glossary of terms, abbreviations
- Short quiz



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