GLOBAL REGULATORY
SOLUTIONS & SERVICES

AN ISO 9001 & 27001 COMPANY

Clinical Documentation supporting Core Labels for Generics/OTC products

Dr. Aswin Kumar Allupati, MBBS
Senior Manager –Medical Expert
Freyr Solutions

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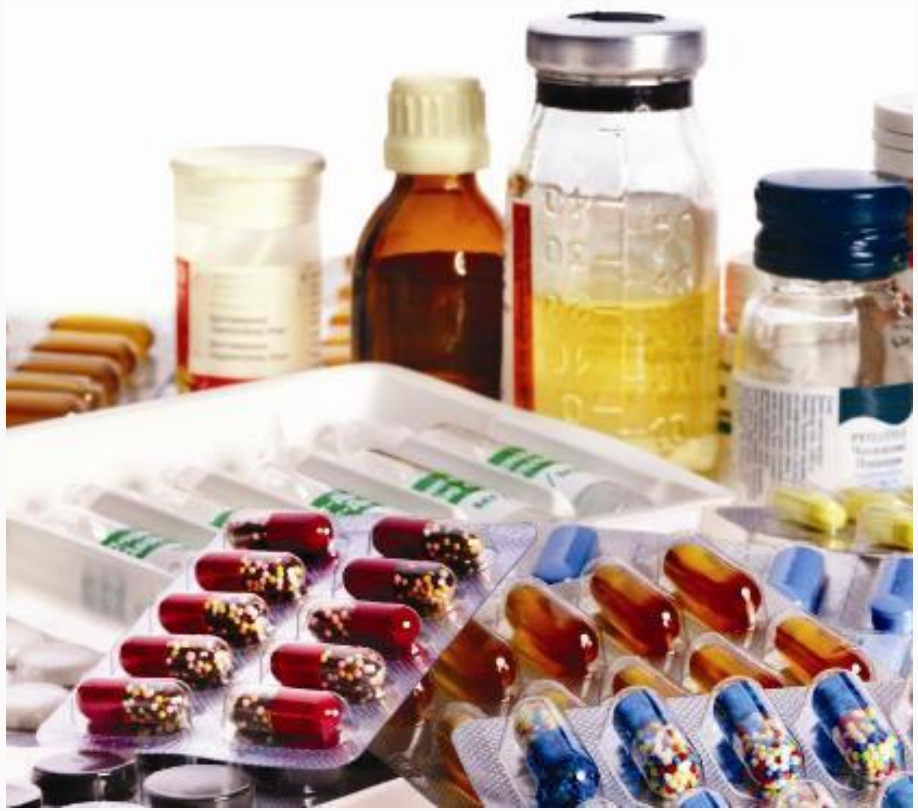
Commonly Used Labels in Different Regions

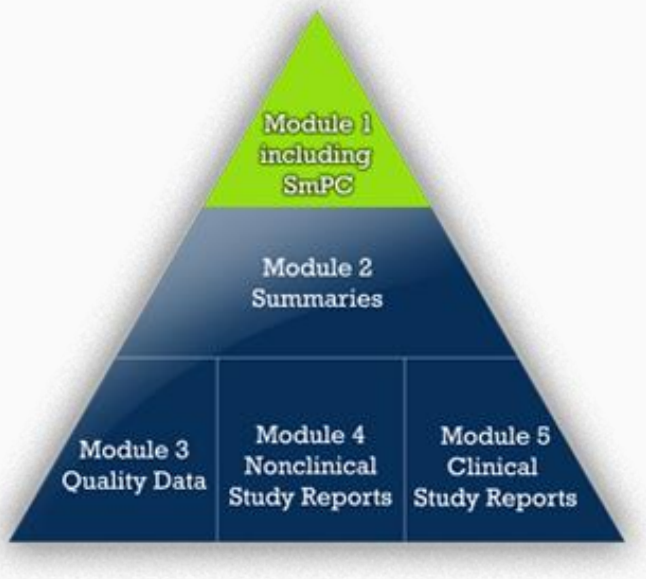
- EU label - SPC
- UK label - SPC
- US label - USPI/Drug Facts
- Australian Label- AU PI
- Japanese Label
- South African Label
- Our own Indian pack inserts

Common Products as OTC

- Analgesics
- Cough Syrups
- Cold and Flu Combinations
- Antacids
- Vitamins
- Food Supplements
- Anti-Diarrhea Medicines
- Anti-Allergy

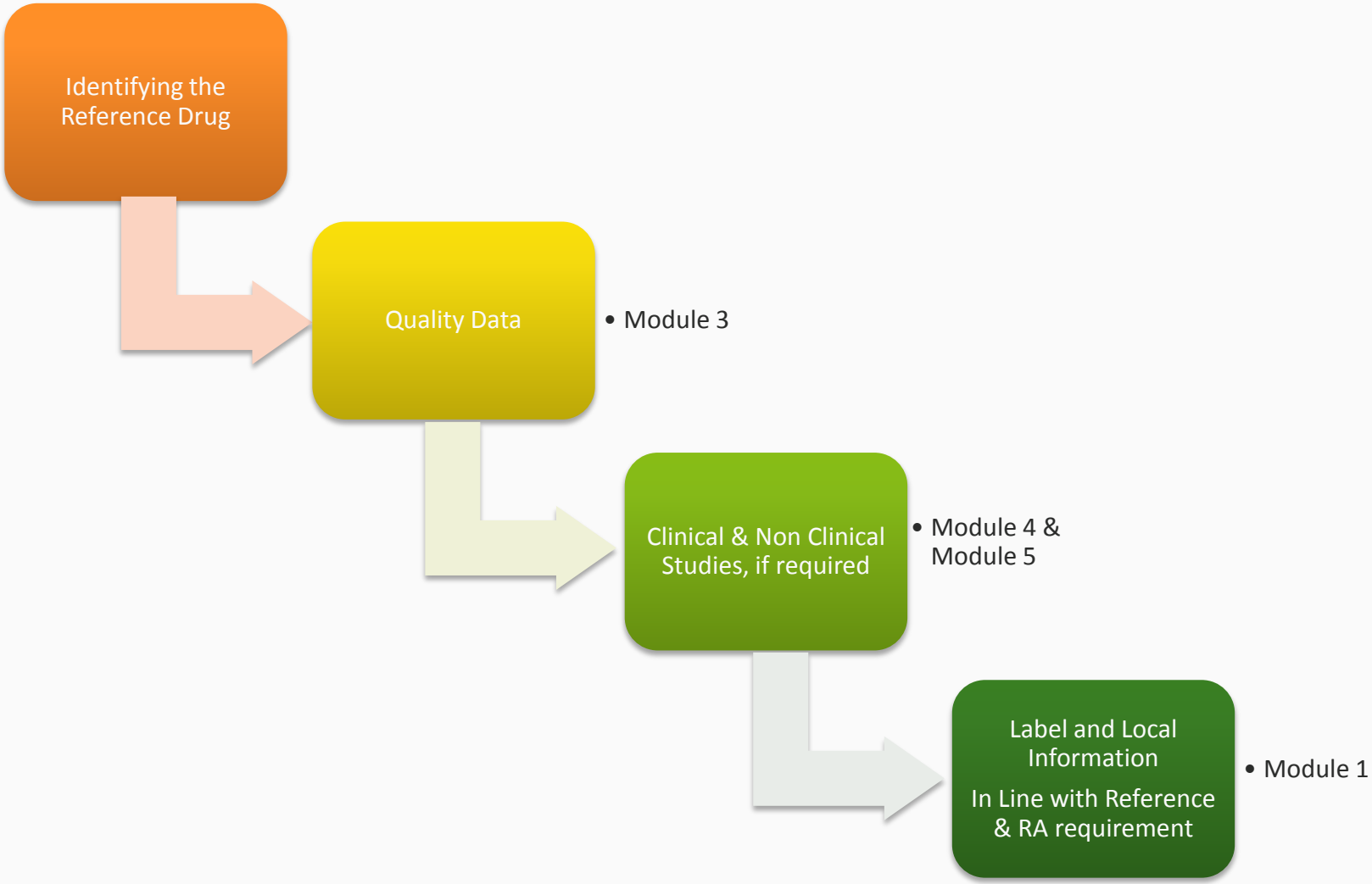


Usual CTD & Label Preparation Process in EBM



- Quality Data • Module 3
- Non Clinical Studies • Module 4
- Clinical Studies • Module 5
- Summaries • Module 2
- Label and Local Information • Module 1

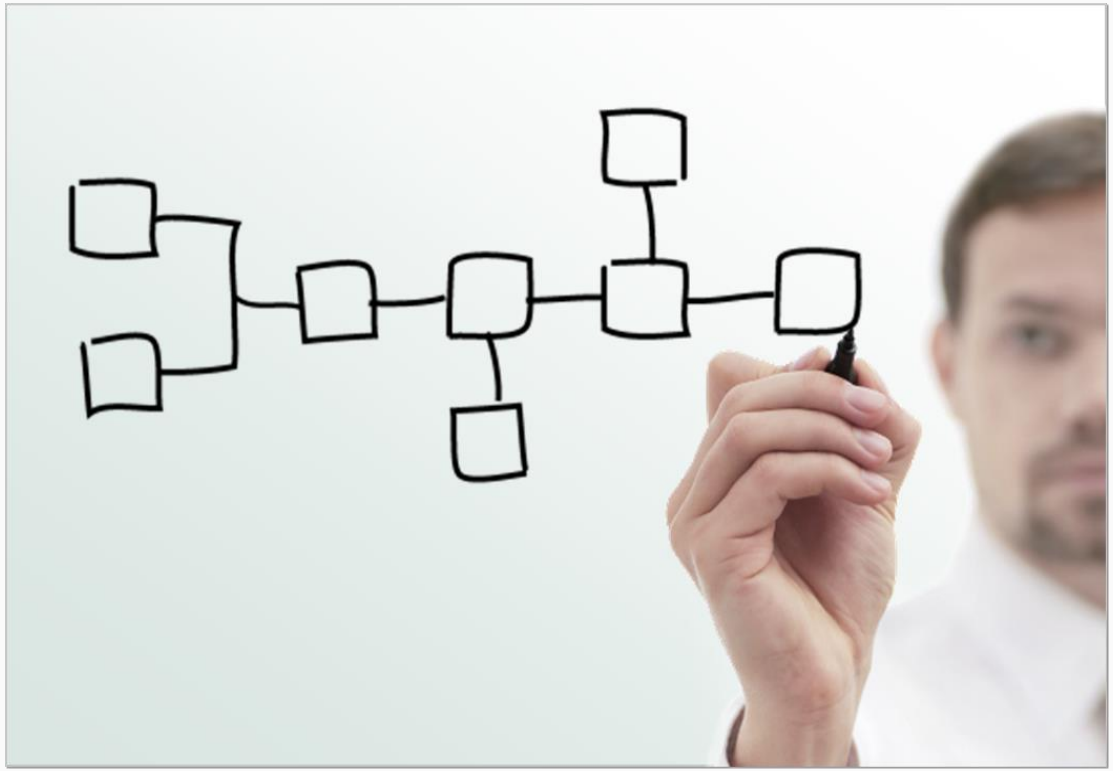
Usual CTD & Label Preparation Process in New Generics



Scenario 1

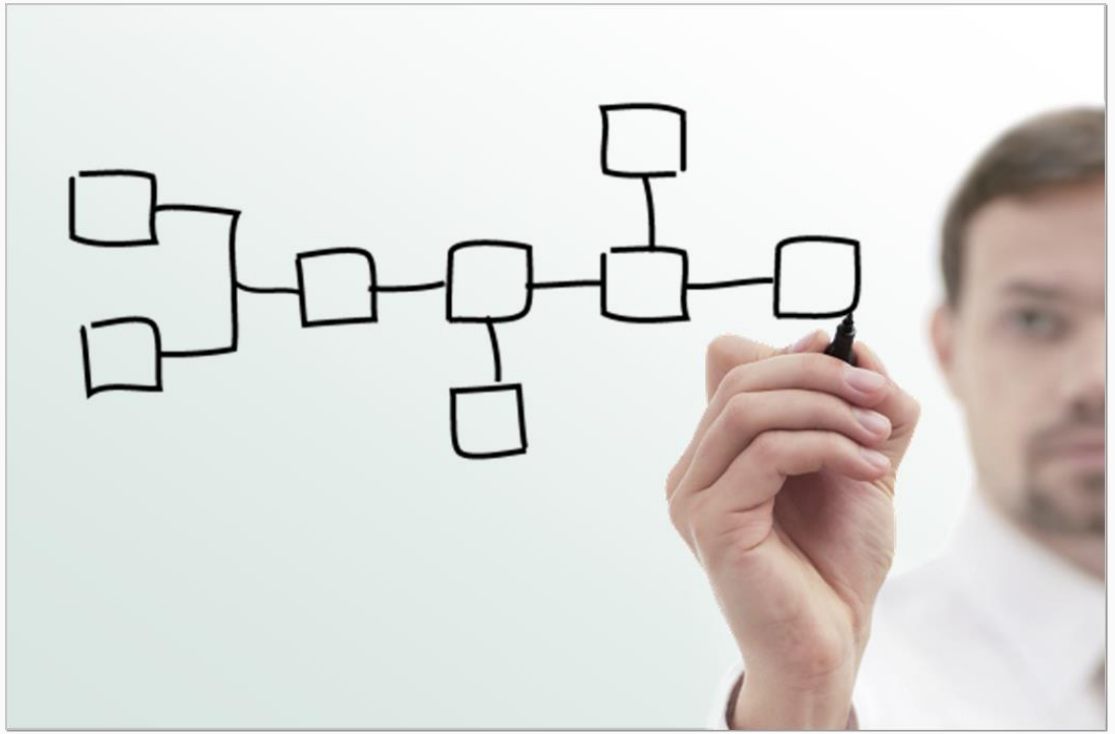
- Drug A has vomiting as Adverse event in Product Label in Country X and not in Country Y.

- If there is vomiting reported as an AE in Country Y, should it be considered as a Expected Event or an Unexpected Event?



Scenario 2

- Drug D has been approved for Indication I in Country X and not in Country Y.
- If a person is prescribed Drug D for Indication I in Country Y by a Physician, will it be an off-Label Use ?

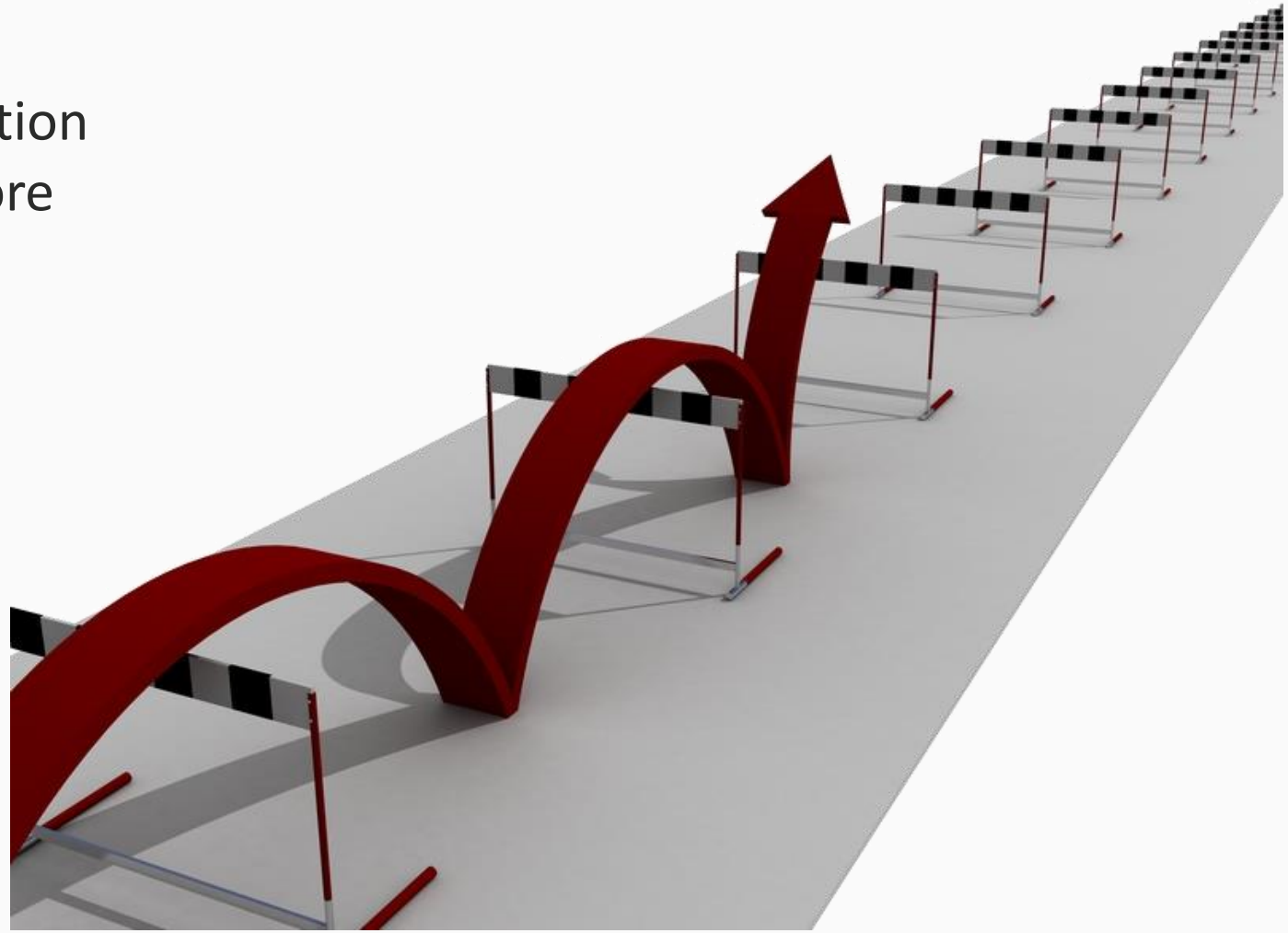


Challenge

- Harmonization
- Creation of Common Minimum Information- Ball Park 80%
- Creation of Core Data Sheet or Core Safety Information

Challenge for creation of CDS

- Reverse engineering
- Identification of scientific information to support the proposed text in core labels
- Creation of clinical overviews to support



Sections of Clinical Overview

- Product Development Rationale
- Overview of Biopharmaceutics
- Overview of Clinical Pharmacology
- Overview of Efficacy
- Overview of Safety
- Benefits and Risks Conclusions
- Literature References

Reference:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002723.pdf

Safety

- Safety is the most important priority in any CDS even if it is an OTC
- Importance of company safety database
- Importance of any regulatory warnings or advisories
- Safety limits as per regulations

Evidence based Medicine

- Metanalysis
- COCHRANE reviews
- Expert group recommendations

Recent Regulatory Advise

- Public Assessment Reports
- PRAC Recommendations

  The Pharmacovigilance Risk Assessment Committee (PRAC) is the committee at the European Medicines Agency that is responsible for assessing and monitoring safety issues for human medicines

- FDA Warnings
- OGD Guidance

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Questions?

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Thank You!

US Headquarters	103 Carnegie Centre, Suite 300, Princeton, NJ – 08540
North America Operations Center	150 College Road West, Ste 102, Princeton NJ – 08540 Phone: +1 908 483 7958
UK	1 Bell Street, Maidenhead, Berkshire, SL6 1BU, UK Phone: +44 2037 012379
India Global Operations Center	Lanco Hills Technology Park, Manikonda, Hyderabad, India Phone: +91 40 4848 0999

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