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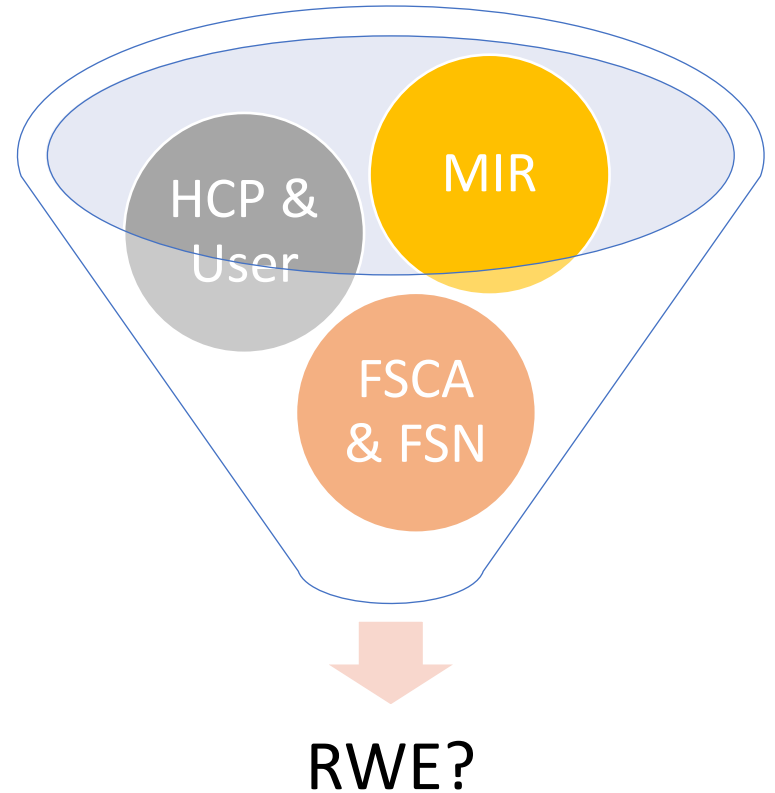
# Post-market surveillance and real-world evidence

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# Why Real World Evidence?

- Extract knowledge from data sources
- Identify relevant data sources
- Specify analysis needs
- (improve data quality)



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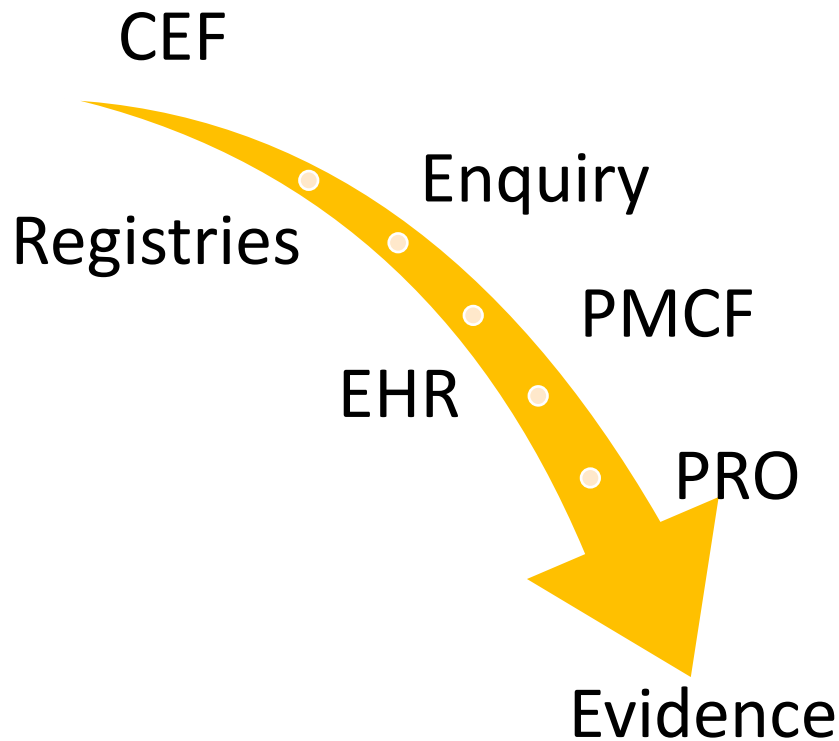
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# Increasing usage of data in PMSV

- Merge knowledge
- Identify signals
- Risk-based approach



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# Some challenges

- Acquisition of data
  - Clinical and medical
- Data anonymization
- Establish data sources
- Implement tools to utilize the data



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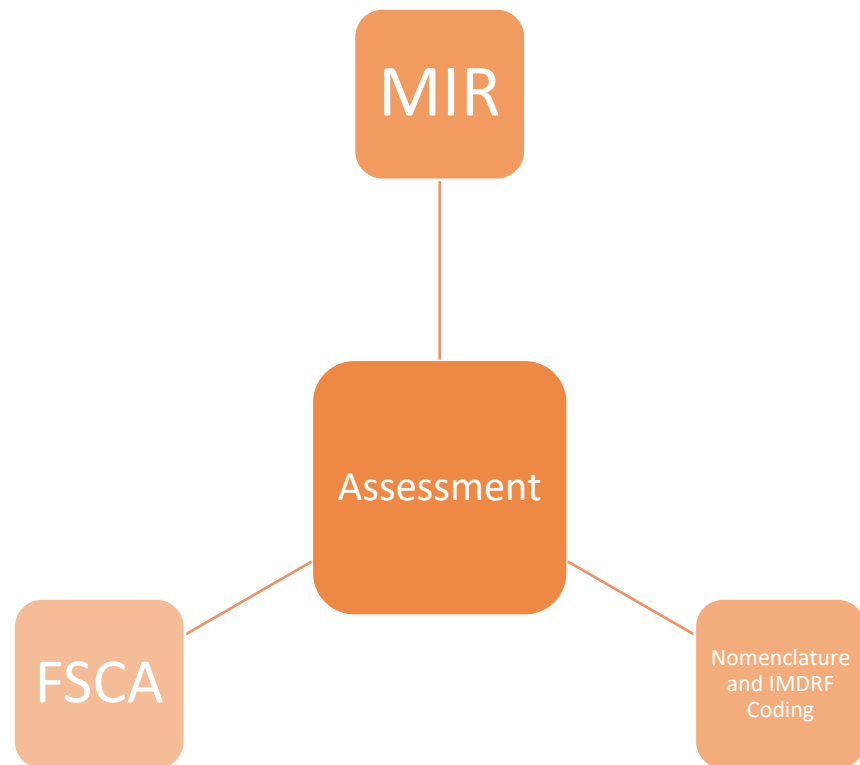
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# Our data driven approach

- Start with the basics
- Include easy-to-use data
- Build signal detection
- Implement NLP and LLM (MLM)
- Based on IMDRF Coding
  - EMDN & GMDN
  - Nomenclature levels



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# Utilization of data (start using your data)

- Quality is never sufficient
- Identify the needs
- CORE-MD tool is a proof for data exploitation

Need for **data aggregation** tools to generate **new value** from existing information, potentially useful for different purposes!



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**CORE-MD**, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.



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For more information, visit: [www.core-md.eu](http://www.core-md.eu)



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