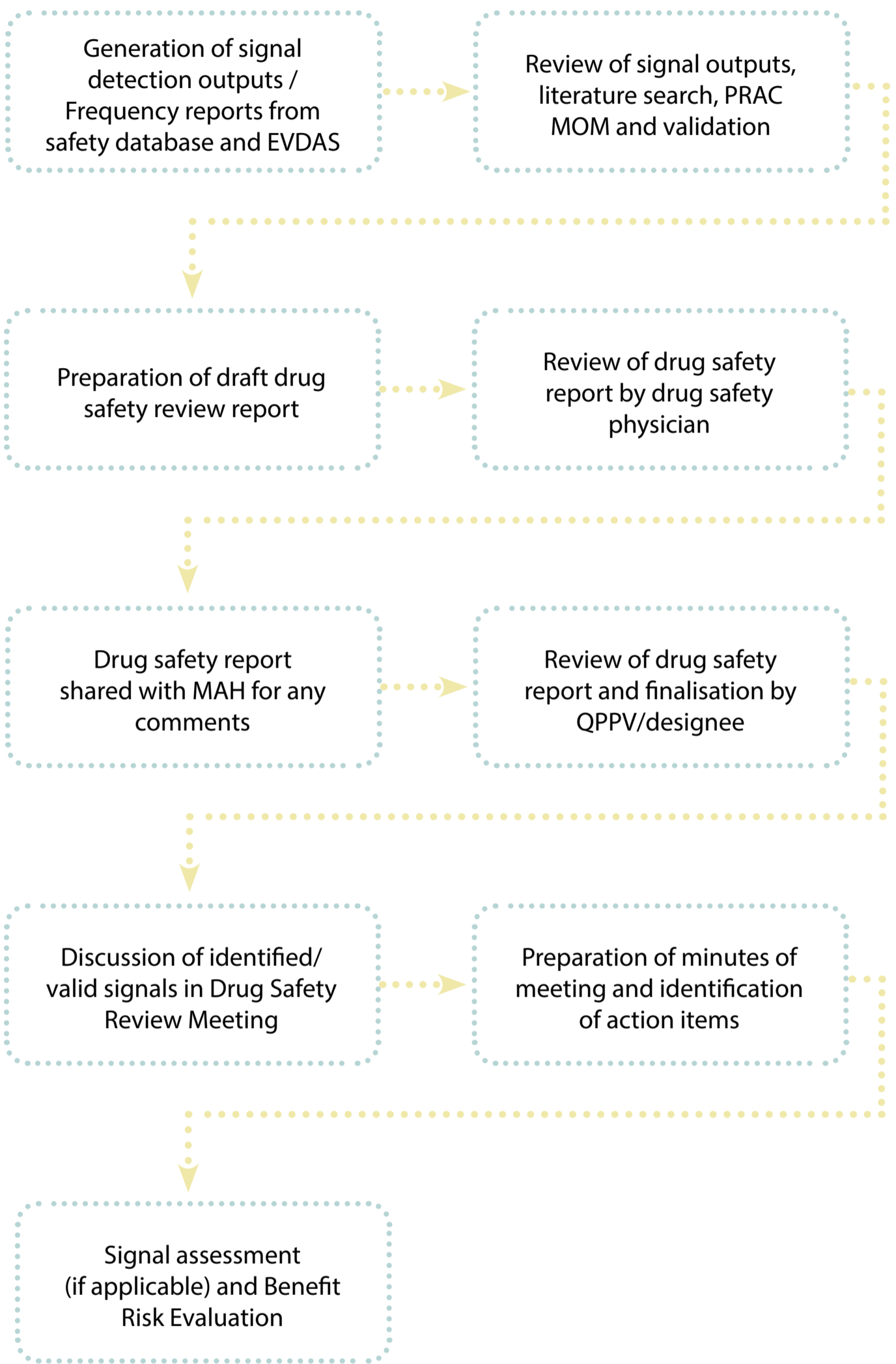


Flow chart to illustrate the process of signal generation, detection and evaluation



Further recommended actions based on outcome of safety review meeting:

- Further monitoring of signal
- Recommendations of SmPC updates
- Discussion with Competent Authorities in reference to valid signals
- Urgent safety restrictions
- Withdrawal of product from the market
- No further action required

ELC Group provides a full coverage of EU and global LQPPV services and also ensure that all of the requisite pharmacovigilance activities are duly taken into account.



Concept to Safety

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