A Pragmatic Framework for Managing a Large Evidence Base in SLR for JCA Oncology Submissions

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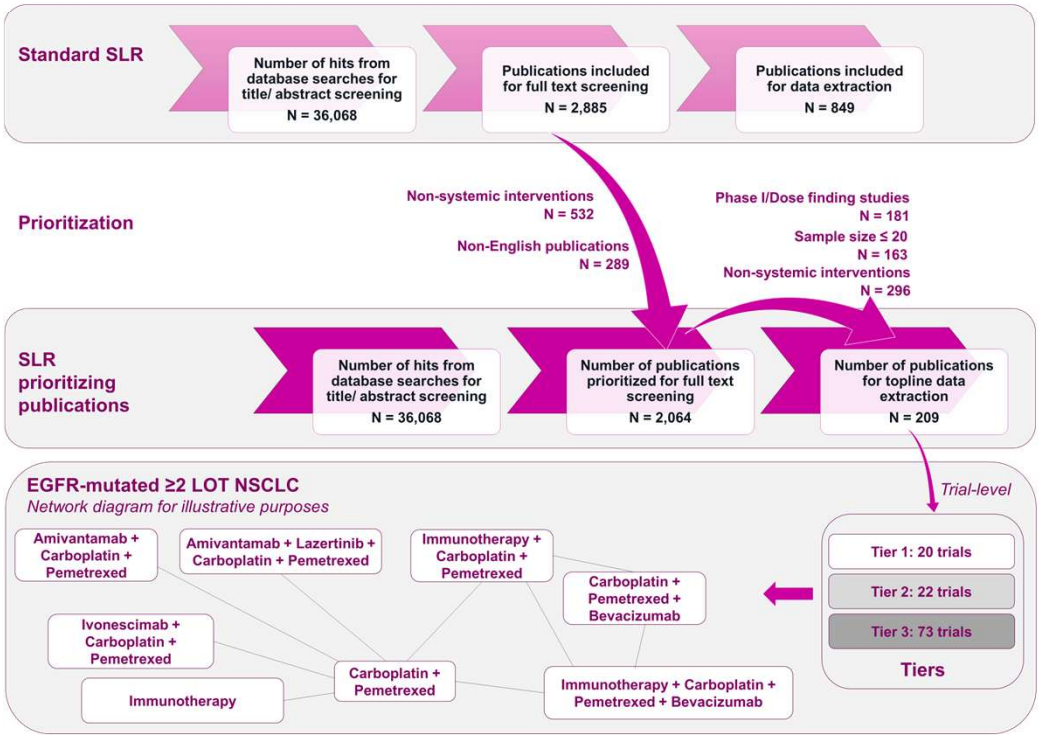
INTRODUCTION

- The implementation of Joint Clinical Assessments (JCAs) poses significant operational and methodological challenges. Pharmaceutical companies need to prepare dossiers under increasingly compressed timelines, often while the European Medicines Agency (EMA) review is still underway. Multiple predicted JCA PICOs (Population, Intervention, Comparator, Outcome) trigger comprehensive systematic literature reviews (SLRs) which generate a high volume of study hits following database searches, substantially increasing the burden of screening and project timelines. Further, PICO proliferation and heterogeneous evidence bases complicate indirect treatment comparisons (ITCs).
- Addressing these demands calls for agile, flexible workflows capable of delivering high-quality comparative evidence under significant time pressure. In this context, we propose a structured prioritization framework to support the selection of trials for inclusion into the SLR and ITC for JCA submissions, which we illustrated based on a SLR for EGFR+ advanced/metastatic non-small cell lung cancer (a/m NSCLC).

METHODS

- **A systematic literature review** was conducted to identify clinical trials evaluating the efficacy and safety of treatments for EGFR+ a/m NSCLC in patients who had received ≥1 prior line of therapy (LOT). Searches were performed in EMBASE, MEDLINE and the Cochrane Central Register of Controlled Trials. During title/abstract and full-text screening, a tailored **prioritization strategy** was applied to deprioritize studies of non-systemic interventions, phase I or dose-finding studies, studies with small sample sizes, and non-English publications. **Topline data extraction** was performed to identify trials that evaluated relevant interventions in the target population as defined by the predicted JCA PICOs. Data extraction captured key study characteristics, including design (randomized controlled trials [RCTs] and single-arm studies), intervention evaluated, population features (prior therapies, EGFR mutation status, central nervous system metastases, geographic region) and availability of overall survival (OS) and progression-free survival (PFS) data.
- Studies were categorized into tiers: **Tier 1 –** trials evaluating relevant treatments in the target population as defined by the predicted JCA PICOs; **Tier 2 –** trials evaluating relevant treatments per predicted JCA PICOs in any a/m NSCLC population; **Tier 3 –** trials evaluating other treatments in a broader pretreated a/m NSCLC population. **Evidence networks** were drafted based on the Tier 1 trials to verify that all relevant comparator treatments were part of an interlinked network of RCTs.

RESULTS



- A total of 36,068 records were identified for title/abstract screening. Of these, 2,885 publications progressed to full-text review, and 849 citations were initially deemed eligible for data extraction. Applying the prioritization strategy substantially streamlined the evidence base: the full-text review set was reduced to 2,064 publications, and the data-extraction set was narrowed from 849 to 209, improving both efficiency and focus for subsequent analyses.
- Following topline data extraction, studies were categorized into evidence tiers. Tier 1 comprised 20 trials, representing the highest-priority evidence base.
- Networks diagrams confirmed inclusions of all relevant interventions in tier 1.
- Carboplatin + pemetrexed emerged as a common comparator, forming a central anchor across the available RCT evidence.

CONCLUSIONS

- A structured prioritization and tiering framework did streamline evidence identification and selection of relevant studies for evidence synthesis in a case study of EGFR-mutated a/m NSCLC patients.
- The proposed framework provides a scalable, pragmatic solution for generating high-quality comparative evidence within the constraints of the JCA process.

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