OBJECTIVE: To describe and compare systematic literature review (SLR) methodological requirements from health technology assessment (HTA) agencies in different jurisdictions around the world. To critically evaluate the submission of SLRs presented in HTA assessments based on the methodological requirements from HTA agencies in different jurisdictions around the world.

RESULTS

HTA requirements for SLRs

Type of SLR
- An HTA website included information regarding the type of literature review required to provide evidence for a product submission. The HTA requirements for the SLR are the most important type of literature review (Table 1).
- Apart from NICE and IOEID, all other agencies reviewed at least one SLR of clinical data and were interested in inclusion criteria of comparative data. This is the case with the guidance from EUnetHTA, given the objective is a clinical assessment.
- SLRs of non-economic evidence (economic evaluation, model inputs such as costs and resource use estimates, utilities) are only required by the HTA agencies, but no NICE specified SLR of economic evidence (Table 1).

Timing of SLR conduct before submission
- To ensure that the most recent search results are available for authorities, NICE and IQWiG specify that the submission update of SLRs of the clinical data should be performed less than 12 months prior to the submission (Table 1).

Methodological guidance
- Overall, HTA guidance documents recommend considering the Centre for Reviews and Dissemination (CRD) guidance (2009) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (2009) for the SLR (Table 1).
- NICE and IQWiG guidance for SLRs are the most prescriptive, whereas the others have fewer explicit requirements. The recent guidance from EUnetHTA addressed the needs of most European HTA agencies.

Evaluation of SLR methodology adopted in HTA submissions
- Across five assessments (NICE, IQWiG and EUnetHTA), included in the evaluations, the guidance on the conduct of the SLR was not available in the NICE guidance. The authors speculate that the SLR may not have performed in these specific cases due to the availability of evidence from head-to-head clinical trials.
- Consequently, evaluation or consideration of methodology adopted in the EUnetHTA, IQWiG and NICE SLR submissions is not possible.
- Assessments were conducted to determine whether the SLR met the requirements for the following: search strategy, data extraction, and quality assessment.
- Evaluation of SLR methodology was performed for the following: search strategy, data extraction, and quality assessment.

D I S C U S S I O N  &  C O N C L U S I O N S

- The most stringent guidance for SLR methodology was seen in Europe (UK and Germany) and Australia whereas the North American (FDA) guidelines for the conduct and documentation of evidence development varied.

M E T H O D S

Methods
- Websites of the most prominent HTA agencies were searched to identify guidance documents detailing SLR requirements. The websites of the following cross-border agencies were searched: Australia (NICE), Canada (CATHT), England (NICE), France (HAS), Germany (G-BA/IGW), Ireland (ICRF), Scotland (SMIC), Sweden (SIV, ULS), USA (AMCP ICER), Thailand (PHE) and Europe (EUnetHTA).
- In addition, clinical assessments (LAs) from EUropeUS were identified for the time period of 2014-2019 for oncology and ophthalmic products. The corresponding submissions were obtained from the websites of NICE and IQWiG.
- Searches were conducted in May 2019 and an update was done in September 2019. Information from the relevant source was extracted based on a predefined data set, a list following which is a descriptive overview of the main findings was prepared and reported.

T A K E  H O M E  M E S S A G E:
- For all reviews, besides comprehensiveness, transparency in the methodology and the minimization of bias is key to the provision of relevant evidence for national HTAs.
- Key differences between HTA agency requirements must be considered when developing an SLR to be used submissions across global markets.
- SLRs conducted for the purposes of HTA submission generally conformed with the different methodological requirements from HTA agencies in different jurisdictions around the world.

REFERENCES
- Please see QR code for references.
REFERENCES
