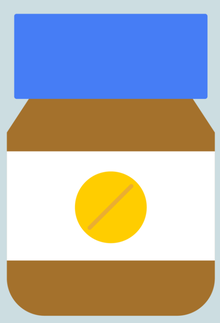

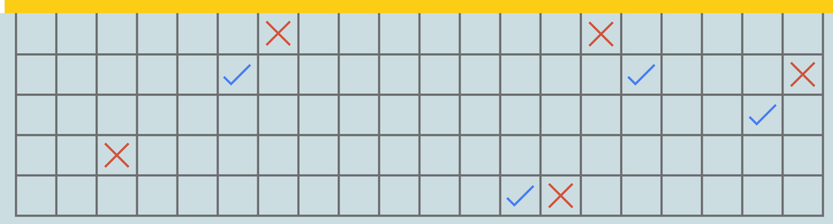

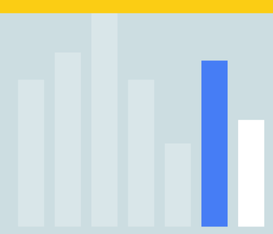

Building bridges between drug regulation, HTA and clinical guidelines

M.A. Hogervorst
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OBJECTIVES

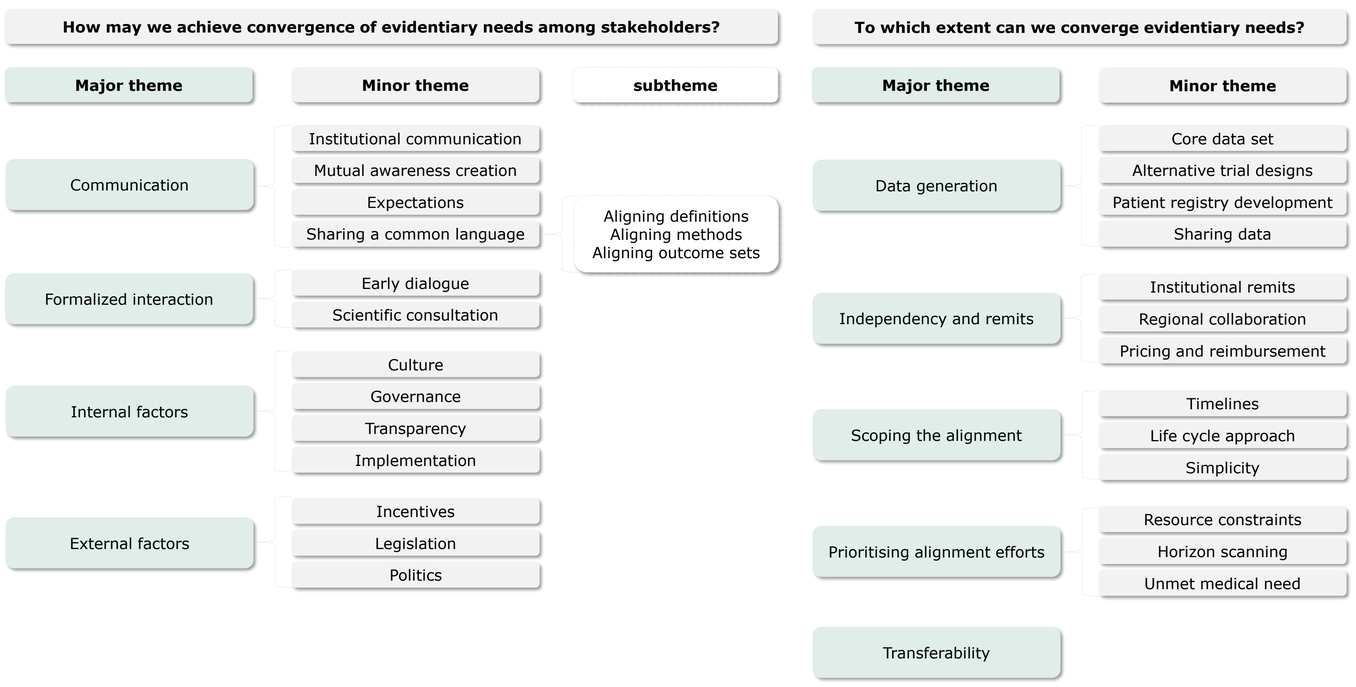
This study discusses tangible ways to improve synergies among regulatory, HTA and clinical guideline development processes. The aim was to discover how convergence of evidentiary needs among stakeholders may be achieved, and to identify to which extent converge can be achieved.

METHODS

Eight online dual moderator (mini) focus groups were organized, contextualised within the case studies diabetes mellitus (DM), head and neck cancer (HN), multiple sclerosis (MS) and myelodysplastic syndromes (MDS). Forty-two experienced (over 10 years) regulators, HTA representatives and clinical guideline developers participated.

RESULTS

All Themes Discussed By Participants in Focus Groups



Four of The Major Themes Highlighted

Improve Mutual Awareness

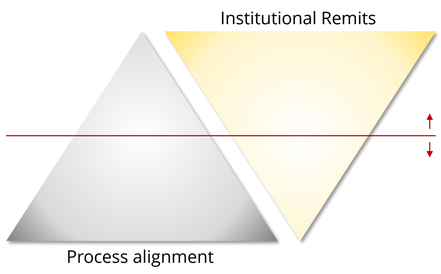
Enlarge contextual considerations in decision-making

Managing expectations allows for anticipation

A common language (methods, definitions, (IT) systems and procedures) may prevent miscommunication

Value Institutional Remits

Assessment, deliberation and decision-making should remain independent



Formalize Interaction

Early dialogue should be instituted to develop a core data set

Evidence should not be aligned, it should include all required elements for all decision-makers

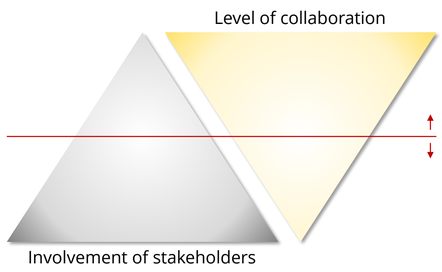
All stakeholders and countries should be active involved *(patients and clinicians, smaller or less resourced countries)*

Appropriate Level of Collaboration

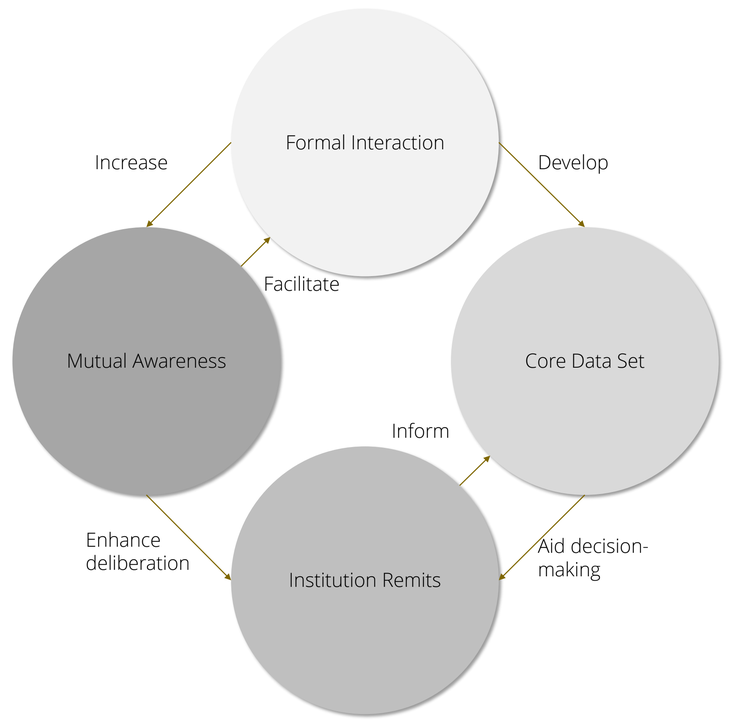
Levels of collaboration range from sharing information to collaborative decision-making

Decisions may be difficult to align across jurisdictions due to differences in healthcare organization and economic context

For some (smaller) countries or institutions with shared interests, regional shared decision-making may make sense



Linkage Between These Four Themes



CONCLUSION

Improving synergy always involves trade-offs, it is key is to find the right balance between the identified strategies

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