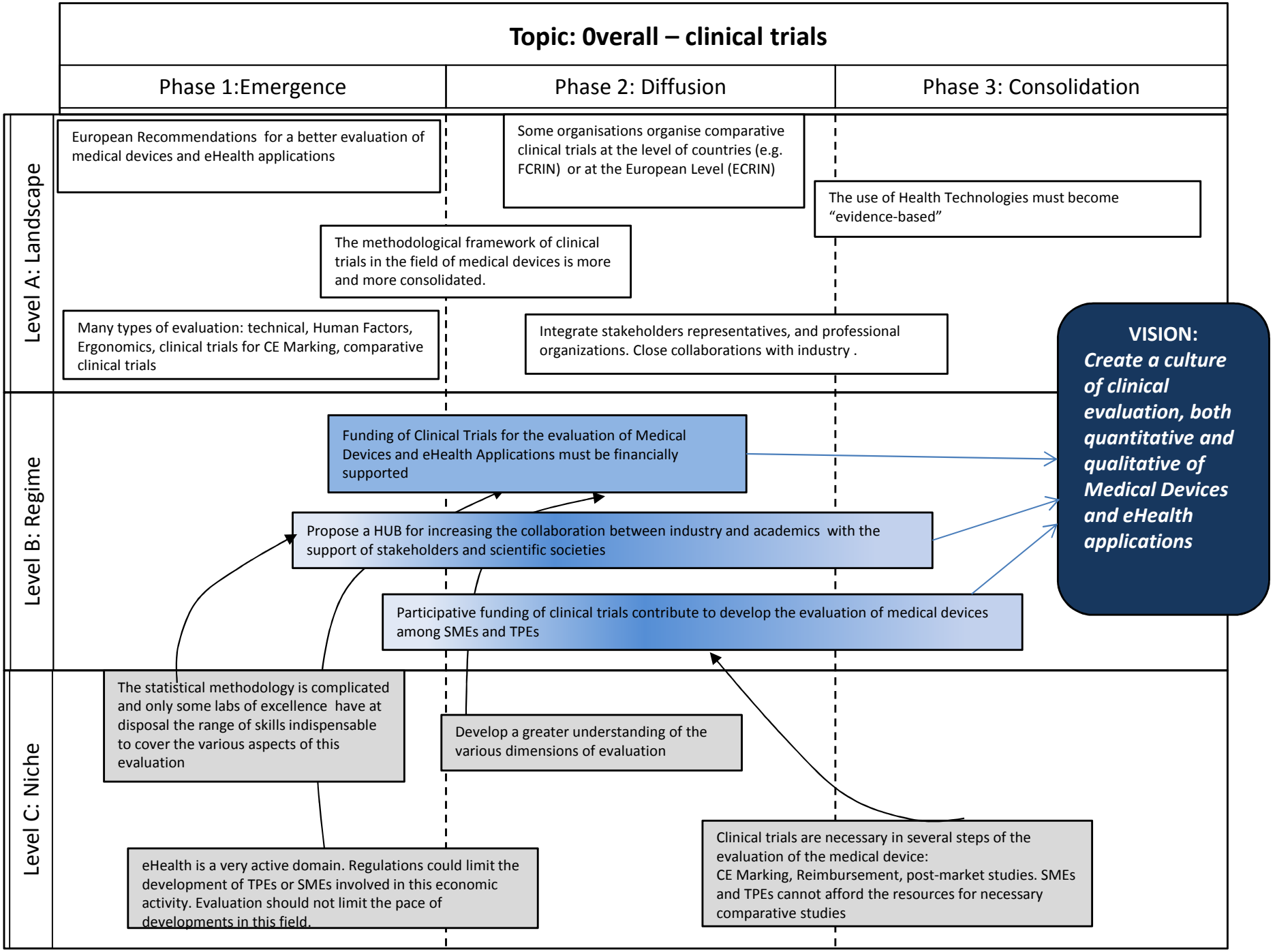
Topic: 0verall – clinical trials
Phase 1:Emergence
Phase 2: Diffusion
Phase 3: Consolidation
Level A: Landscape
Level B: Regime
Level C: Niche
European Recommendations for a better evaluation of medical devices and eHealth applications
Some organisations organise comparative clinical trials at the level of countries (e.g. FCRIN) or at the European Level (ECRIN)
The use of Health Technologies must become "evidence-based"
The methodological framework of clinical trials in the field of medical devices is more and more consolidated.
Many types of evaluation: technical, Human Factors, Ergonomics, clinical trials for CE Marking, comparative clinical trials
Integrate stakeholders representatives, and professional organizations. Close collaborations with industry .
VISION:
Create a culture of clinical evaluation, both quantitative and qualitative of Medical Devices and eHealth applications
Funding of Clinical Trials for the evaluation of Medical Devices and eHealth Applications must be financially supported
Propose a HUB for increasing the collaboration between industry and academics with the support of stakeholders and scientific societies
Participative funding of clinical trials contribute to develop the evaluation of medical devices among SMEs and TPEs
The statistical methodology is complicated and only some labs of excellence have at disposal the range of skills indispensable to cover the various aspects of this evaluation
Develop a greater understanding of the various dimensions of evaluation
eHealth is a very active domain. Regulations could limit the development of TPEs or SMEs involved in this economic activity. Evaluation should not limit the pace of developments in this field.
Clinical trials are necessary in several steps of the evaluation of the medical device:
CE Marking, Reimbursement, post-market studies. SMEs and TPEs cannot afford the resources for necessary comparative studies