Bridging the Gap: User Engagement in Developing and Implementing Digital Medication Adherence Technologies

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OBJECTIVE

- To create a comprehensive framework for the development and implementation of digital medication adherence technologies (DMATech), focusing on critical stages where engagement of medication users (MUs) adds significant value

METHODS

- _Task 1. Development of a comprehensive framework outlining the key stages of developing and implementing DMATechs_
  - Targeted literature review
  - Iterative process by a group of 7 adherence/DMATech experts
- _Task 2. Mapping MU engagement opportunities in developing and implementing DMATechs_
  - One-day, in-person workshop with patient representatives, and adherence experts in Budapest, Hungary, on November 29, 2023
    - Selecting framework phases could benefit from MUs engagement
    - Suggesting potential types and modes of MUs engagement
    - Rating the importance of each step in the framework using a Likert scale ranging from 1 for 'Not at all important' to 5 for 'Very important'
  - Nominal group technique was used to facilitate discussion and reach consensus
  - Data analysis
    - A step with an average ranking score of ≥4.0 was considered a high-importance step.
    - The interquartile range (IQR) was employed to assess consensus strength on these ratings, with an IQR>1 indicating a lack of consensus
    - Differences between the ratings of the patient representatives and experts were tested with the Mann-Whitney U test

RESULTS

- The DMATech framework included three phases: 'Innovation', 'Research and Development', and 'Launch and Implementation', each encompassing multiple steps (**Figure 1**)
- The attendees included five patient representatives and nine adherence experts from various regions (Europe, North America, and Middle East)
- Identified crucial phases for MU input: context analysis, ideation, proof of concept, prototype creation, DMATech's iteration, critical evaluation, healthcare implementation, real-world assessment, and improvement (**Figure 2**)
- There was a divergence of consensus regarding the importance of MUs engagement in regulatory, financial, and marketing aspects (**Figure 2**)
- The ratings given by patient representatives and adherence experts showed no statistical differences for any of the framework's steps
- Participants concluded that it is not feasible to propose general recommendations for types and modes for MU engagement; instead, their assessments must be conducted on a case-by-case basis

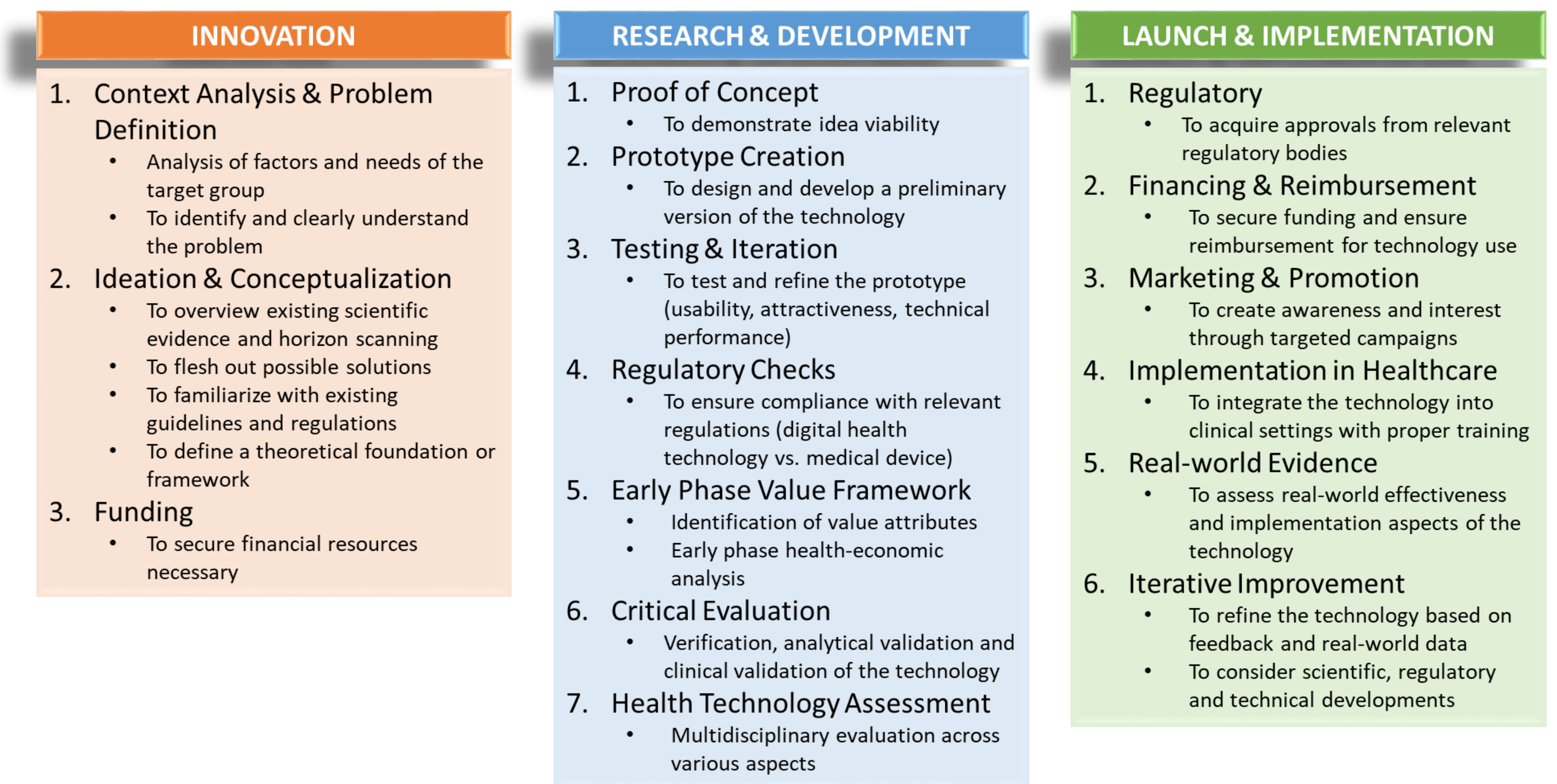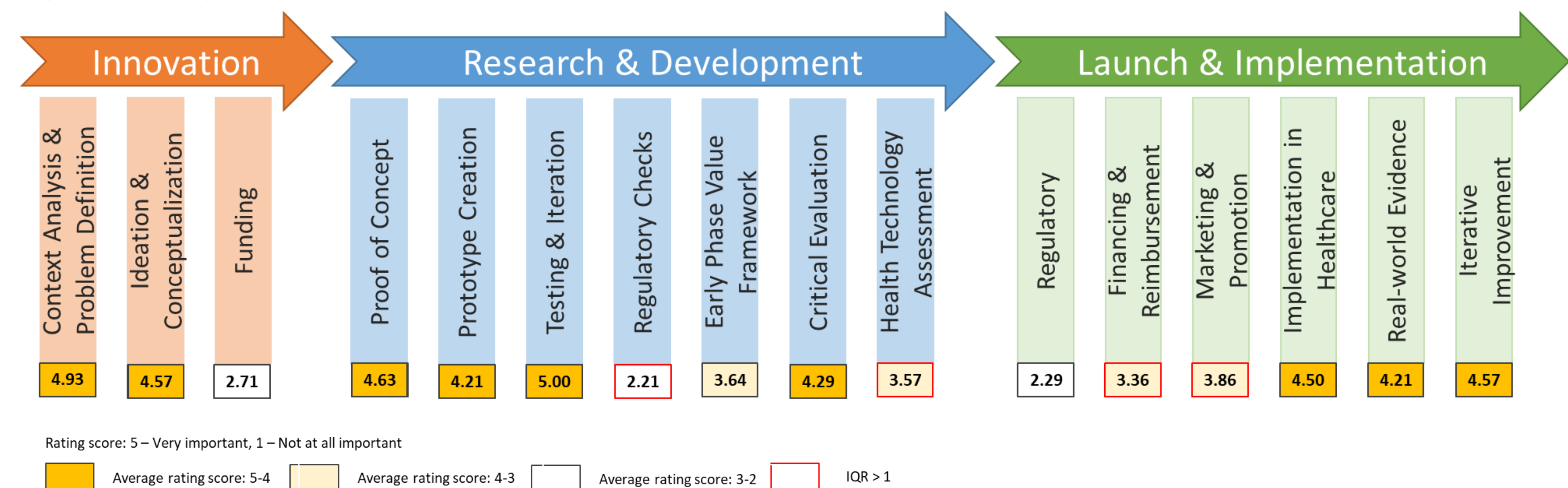**Figure 1.** DMATech blueprint: from idea to implementation in healthcare

INNOVATION	RESEARCH & DEVELOPMENT	LAUNCH & IMPLEMENTATION
1. Context Analysis & Problem Definition • Analysis of factors and needs of the target group • To identify and clearly understand the problem	1. Proof of Concept • To demonstrate idea viability	1. Regulatory • To acquire approvals from relevant regulatory bodies
2. Ideation & Conceptualization • To overview existing scientific evidence and horizon scanning • To flesh out possible solutions • To familiarize with existing guidelines and regulations • To define a theoretical foundation or framework	2. Prototype Creation • To design and develop a preliminary version of the technology	2. Financing & Reimbursement • To secure funding and ensure reimbursement for technology use
3. Funding • To secure financial resources necessary	3. Testing & Iteration • To test and refine the prototype (usability, attractiveness, technical performance)	3. Marketing & Promotion • To create awareness and interest through targeted campaigns
	4. Regulatory Checks • To ensure compliance with relevant regulations (digital health technology vs. medical device)	4. Implementation in Healthcare • To integrate the technology into clinical settings with proper training
	5. Early Phase Value Framework • Identification of value attributes • Early phase health-economic analysis	5. Real-world Evidence • To assess real-world effectiveness and implementation aspects of the technology
	6. Critical Evaluation • Verification, analytical validation and clinical validation of the technology	6. Iterative Improvement • To refine the technology based on feedback and real-world data • To consider scientific, regulatory and technical developments
	7. Health Technology Assessment • Multidisciplinary evaluation across various aspects	

Figure 2. Ratings of development and implementation steps of DMATech

Innovation			Research & Development							Launch & Implementation					
Context Analysis & Problem Definition	Ideation & Conceptualization	Funding	Proof of Concept	Prototype Creation	Testing & Iteration	Regulatory Checks	Early Phase Value Framework	Critical Evaluation	Health Technology Assessment	Regulatory	Financing & Reimbursement	Marketing & Promotion	Implementation in Healthcare	Real-world Evidence	Iterative Improvement
4.93	4.57	2.71	4.63	4.21	5.00	2.21	3.64	4.29	3.57	2.29	3.36	3.86	4.50	4.21	4.57

Rating score: 5 – Very important, 1 – Not at all important

- ▮ Average rating score: 5-4
- ▮ Average rating score: 4-3
- ▯ Average rating score: 3-2
- ▯ IQR > 1

CONCLUSIONS

- The observed divergence in consensus regarding the importance of MUs engagement in regulatory, financial and marketing steps highlights the need for targeted educational programs to address potential knowledge gaps
- Future research could explore innovative methods for engaging MUs, tailoring input mechanisms to specific user needs

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