Constructing a Criteria Assessment Framework for Early Medtech Innovation Projects at China's Proof of Concept Centers

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***Abstract*—Proof of Concept (POC) plays a key role in reducing the risk of failure and increasing the success rate of translating technology innovation ideas into prototyping and is often applied in technology transfer processes. In recent years, China has introduced public policies to support the construction of proof-of-concept centers to encourage medical technology (medtech) Research and Development (R&D). A comparative case study was done to explore the commonalities and differences between current China and the US practice of government-led proof of concept centers' project assessment criteria. Based on the findings, this research consolidated a criteria assessment framework for early-stage medtech project selection, in hopes to serve as an assessment tool to clarify the selection criteria at proof-of-concept medical technology centers in China.**

Keywords-Proof of concept; medical technology transfer; medical technology innovation.

I. INTRODUCTION

Data from China's Patent Survey Report 2023 revealed that the patent-to-industrialization rate of the pharmaceutical manufacturing industry is 43%, performing significantly lower than that of other types of manufacturing industries, for instance, automobile industry at 63.3%, leaving room for improvement [1].

Driving medtch innovation requires more than market power. At a national level, refining the innovation system can help accelerate early-stage technology projects into industrialization stage. Proof of Concept Centers (POCCs) are a type of infrastructure to help early-stage technology translation, and they have been rapidly growing in China. The idea of proof of concept is recognized as part of the Technology Readiness Level (TRL) pinpointed at the early stage of technology development cycle. The purpose is to test and validate technology components, measure technology progress, and plan for future inputs needed to increase technology maturity. The significance of the proof of concept is to provide technology transfer milestone guidance and financing for high-potential early-stage R&D projects under controlled risk assessment conditions [2].

However, there are operational challenges yet to be addressed and optimized in practice. One of them is to assess the medtech projects applying for POC funding [3]. This research aims at first addressing the evaluation components of POCC samples in China and samples from National Institutes of Health (NIH) Proof of Concept Network, in hope to explain the current commonalities and differences between China and the United States' implementation experiences. Secondly, based on the case study findings, this research aims to consolidate a criteria assessment framework for open discussion on its feasibility in China's POCC setting.

The rest of the paper is structured as follows. In Section II, we present a briefing on POCCs in China and the criteria that two POCCs applied for selecting medtech projects to fund. In Section III, we present two NIH POCCs' project selection criteria and describe the commonalities and differences between China and the US as comparative case studies. Finally, we conclude the work in Section IV.

II. PROOF OF CONCEPT CENTERS IN CHINA

Since 2018, POCCs have gradually been promoted in various provinces and cities in China. A number of POCCs received public endorsement and funding support from local government. For example, in 2022, Beijing Municipal Commission of Science and Technology announced funding support for 12 local POCCs [4], with the total amount of support for a single POCC not exceeding 15 million RMB within three years [5]. Shenzhen Science and Technology Innovation Bureau announced funding support to 10 local POCCs in 2024 [6], and Hangzhou Science and Technology Bureau announced the establishment of 15 POCCs in 2023 [7].

A. Operation Main Body

In terms of medtech-focused POCCs, they are run by different operation bodies such as local government as a public service, hospital in-house service, university-based service, and corporate-owned commercial service. Some of these can be co-founded by a public-private partnership (See Table I).

TABLE I. POCC FACILITIES IN CHINA-SELECTED SAMPLES

Main Body	**POCC Information**	
	Institution Name	***Year of Establishment***
Government	Xi'an High-Tech Medical Device Proof of Concept Center [8]	2023
Hospital	Beijing Friendship Hospital Proof of Concept Platform [4]	2022
University	Medical Proof of Concept Center, Capital Medical University [4]	2022
Corporation	Hangzhou Denuo High-end Medical Device Proof of Concept Center [9]	2022

B. Positioning and Function

The role of a POCC is to assess the potential business value and technical feasibility of medtech research projects at early stage of R&D and inform go/no-go decisions to grant funding for proof-of-concept research and product development. Business advisory services such as project management guidance, entrepreneurship training, intellectual property protection, etc., are also provided at the POCC to help improve the translation success rate of an innovation idea into intellectual property, product development, licensing and commercialization.

Some POCCs include services down the translational stream for prototyping, performance testing and manufacturing, which requires facility investment on hardware, equipment, and testing and laboratory space as capital expenditure for the center [10].

C. Selection for Funding Proof of Concept Projects

A policy text analysis was conducted selecting two government-led POCCs in Beijing (Zhongguancun Administrative Committee) and Hangzhou (West City Science and Innovation Corridor) as examples. Despite the variation in R&D nature of different industries, these two POCCs are positioned to serve projects across multiple industries thus apply a general criterion for project assessment (See Table II).

TABLE II. PROJECT ASSESSMENT OF TWO POCCS IN BEIJING AND HANGZHOU

Assessment dimension	Beijing [10]	Hangzhou [11]
Technology	Key tech breakthrough. Technology readiness level. Intellectual property rights. Relevant award.	Key tech breakthrough. Innovation significance. Intellectual property rights. R&D plan.
Marketing	Expected market scope, expected economic and social benefits, etc.	Target market, user needs. Market positioning and promotion plan. Relevant performance or revenue that has been generated.
R&D capability	R&D experience, research team background.	R&D experience, research team background.
POC plan	Task objectives, assessment indicators, deliverables, implementation cycle, and the total amount of funds to be invested.	Specific objectives, implementation plan and deliverables, with a budget plan for two years of implementation.
Plan for technology transfer or commercialization	Current conditions for technology transfer.	Financing of the project. Company registration at West City Science and Innovation Corridor.

III. COMPARISON WITH NIH POC NETWORK

In 2013, the NIH Centers for Accelerated Innovations (NCAI) program and, in 2015 and 2019, the Research Evaluation and Commercialization Hubs (REACH), formed a nationwide POC network to allocate funding resources to collaborated innovation hubs across 19 states [12].

The NIH Proof of Concept Network focuses on providing funding support and entrepreneurial training to medtech projetcts at the stage of TRL 3 to 5 [13]. The entire TRL spectrum classifies the life cycle from technology R&D to commercial deployment into nine levels [14]. While TRL 1 represent the theoretical principle for an innovative idea, and TRL 9, the last readiness level, represent operational status, TRL 3 to 5 are early-stage levels from hypothesis testing to pre-clinical studies or prototype testing, when applied in medtech setting.

A. Assessment for Funding Proof of Concept Projects

While NIH has specific evaluation metrics for the hubs within its POC network, every hub conducts individual assessment for local medtech projects applying for either NCAI or REACH grants. Table III provides a brief overview of the assessment dimensions from two selected hubs (SPARK, WE-REACH) of REACH 2019 to review their funding applicants.

TABLE III. PROJECT ASSESSMENT OF TWO REACH 2019 HUBS

Assessment dimension	SPARK [15]	WE-REACH [16]
Unmet need	Clinical need Stakeholder perspective Relevant evidence	Unmet human health need significance. User investigation.
Technology	Solution setting. Expected benefit and preliminary data. Intellectual property rights. Tech advancement.	Intellectual property rights. Available information on U.S. Food and Drug Administration predicate devices and systems.
Marketing	Patient target. Market size, and target price of the technology. Market population trends. The competition mix.	The usefulness and novelty of the product. Market identification and scope estimation. Competitive landscape.
R&D capability	Team member credentials. Expertise needed ongoing.	Team member credentials.
POC plan	Total funding required to bring the product to a commercial exit. Project plan and go/no-go decision points.	Primary milestone goal. Evidence to support the proposed POC. Staffing, equipment, and funds needed.
Plan for technology transfer or commercialization	Tech transfer outcome. Financial overlap explained. Estimated long-term return on investment.	Other funding awarded. Pathways to commercialization, including regulatory, reimbursement, etc.
Risk declaration	Define the potential risks (scientific, technical, personnel, market, and commercialization) and the mitigation processes.	Define the potential risks (scientific, technical, personnel, market, and commercialization) and the mitigation processes.
Ethical review	Human subject use and Institutional Review Board approval Institutional Animal Care and Use Committee approval Human Embryonic Stem Cells	N/A

B. *Commonalities and Differences between China and US Case Studies*

By comparing the case studies from China and the US, several commonalities are identified. To start, the assessment frameworks from case studies all include business and economic components, POC implementation and technology transfer plan, to review the projects feasibility and return on investment potential. R&D capability also plays a crucial element for project selection, as it explains the technical skill sets of the entire project development.

The differences are shown as follows. The US case studies put heavy emphasis on clarifying stakeholder perspectives and demands, applying a user-centered approach to clarify project significance, while the China case studies look deeper into honorary credentials of the technical performance, novelty and business forecast. This may be because NIH's network specifically focuses on funding projects at the stage of TRL 3-5, which are relatively early to accumulate credentials, conduct market validation or create sales record, while China's POCCs receive applications from a wider range of TRL status, some of which may result in commercial, real-world feedback.

In addition, the US assessment requires risk declaration from the principal investigator team. Rather than focusing on the potential market performance, the assessment process takes a more risk-averse view to grant funding.

IV. CONCLUSION AND FUTURE WORK

Literature review on current assessment frameworks found a lack of consensus on methods and key variables needed to conduct early stage medtech assessment. The appropriate timing for conducting assessment in the development cycle is not clearly articulated in many assessment as well [17]. The findings from the comparative case studies between China and the US resonate with the literature review. From the case study findings, it is clear that TRL assessment is practiced in some POC settings, but not universally applied. Some raise open-ended questions for principal investigator to describe the maturity of the medtech project, which could lack a systematic method to pinpoint the status quo and track the progress of medtech development after receiving POC funding.

Based on the above-mentioned discoveries, this research proposes a criteria assessment framework (Table IV) as initial draft for POCC project selection practice, applying TRL as a standardized, qualitative analysis for early medtech project's maturity measurement to better identify its status quo and resource demand, and outcome objective setting.

The experience of patients as medtech recipients and healthcare professionals as medtech users will determine the success or failure of the product's clinical performance [18]. Thus, aside from TRL, stakeholder identification and analysis should be thoroughly considered as an influential variable at POC stage to better ensure product design and market positioning.

TABLE IV. CRITERIA ASSESSMENT FRAMEWORK PROPOSED FOR POC

Project criteria	
Unmet need	Clinical need and significance. Stakeholder and end-user investigation and relevant evidence.
Technology feasibility	Setting in which the solution will be utilized. Expected benefit and preliminary research data. Intellectual property rights status. Technology advancement or breakthrough. Current TRL identification.
Business prospect	The primary patient population for use. Market size, and target price of the technology. Market population trends. The competition landscape.
R&D capability	Team member list with credentials and role in the project. Expertise needed for future development.
Implementation criteria	
POC research	Task objectives, assessment indicators, deliverables, implementation cycle, and the total amount of funds to be invested.
Technology transfer or commercialization	Tech transfer outcome to be achieved. Financial overlap with other projects. Estimated long-term return on investment (optional).
Risk declaration	Define the potential risks (scientific, technical, personnel, market, and commercialization) that exist and the mitigation processes available.
Ethical review (If appropriate)	Human subject use and IRB approval. Animal use and IACUC approval. Human Embryonic Stem Cells.

This is working research to construct a POC criteria assessment framework for early-stage medtech projects. Current work is completed based on literature and open online resources available. Since the NIH proof of concept network is a medtech-focused program, and the case studies from China receives projects applications from multi-industries, thus the latter's assessment framework could appear to be relatively general. Further interviews and onsite investigation with Chinese POCC stakeholders should be conducted to obtain constructive feedback. Hospital-based or medtech-specific POCCs should be further explored in order to understand how assessment is conducted.

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