CRITICAL PATH INSTITUTE

Delivering regulatory impact from consortium-based projects

Multiple consortia have been established in the past two decades with the aim of tackling roadblocks in the development of medical products, often by developing new tools to support decision making by regulatory agencies. Here, we highlight lessons learned from these efforts that could help maximize the regulatory impact of consortium-based projects.

Public–private partnerships (PPPs) that bring together key players involved in biomedical research are now a well-established approach to addressing challenges in medical product development. Many of the previously existing barriers to such multi-stakeholder collaborations have been surmounted, and trust has been built across the spectrum of stakeholders — including academic researchers, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organizations and medicines regulators — who have participated in such collaborative efforts1.

Having a neutral and independent facilitator for the platform to provide governance and structure has been a key element in the success of many consortia. However, simply establishing cross-sector consortia does not guarantee a successful outcome. It is crucial to define what the objective is and rally all stakeholders to buy into that objective, as they often have different priorities and expectations. There are also several areas that should be emphasized, which we highlight here.

Read the publication in its original format on nature.com, here. (Subscription required after 6.27.2025).