The New Age of Private Research Funding: Be Careful Out There!

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The days of research funded exclusively from public sources may soon be over. The transition from public to private sector funding has already taken place in some domains of the sciences. For example, over the past 10 years, the efforts of SPACEX, BIGELOW AEROSPACE, and BLUE ORIGIN have slowly supplanted those of NASA. This same shift is now taking place in medical research. The research function at academic medical centers (AMCs) was once funded almost exclusively from public sources such as the NATIONAL INSTITUTES OF HEALTH (NIH). From 2004 to 2012, funding from the NIH fell from \$35.6 billion to \$30.9 billion in real terms, while funding from medical device and biotech firms, foundations, charities, and other private sources collectively grew by \$10.6 billion.¹ In response, AMCs are now seeking more private investment in their research.

The traditional approach to research funding is aligned with the grant application process of an “innovation investor” (e.g., NIH, DOD, etc.). For example, a solo oncologist investigating therapies for checkpoint inhibitors would apply for research funding from the NIH. Any research findings funded through the NIH are then publicly disseminated in the form of publications, reports, and conference presentations. Intellectual property (IP) generated from the research is then retained by the AMC, who commercializes the IP typically through a licensing agreement or a spin-off entity.²

In contrast, private funds from an “innovation benefactor” (e.g. LEUKEMIA AND LYMPHOMA SOCIETY, orphan disease foundations, etc.) with a mission to seek a cure for a particular disease distribute funding to a limited number of academic institutions, which then collaborate on a shared research

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agenda, forming an Innovation Network. In contrast to the innovation investor model, AMC's participating in the Innovation Network investigating an immunotherapy for a single type of cancer, for example, would collaborate and share research results to streamline their efforts. While AMC's still maintain IP generated from research at their own institutions, future profitability of the commercialized therapy is in part distributed back to the innovation benefactor.²

The success of the Innovation Network is dependent upon the orchestrator's ability to uphold these three responsibilities through trust, procedural justice, and joint asset ownership.⁵ Additionally, the overall strength of the innovation network is impacted by the sustainability, or lack of inherent imitability, of its knowledge.⁷⁻⁹ A network is strongest when barriers to imitation and efficacy of IP rights are high.

In the past, the role of the network orchestrator was played by the innovation investor, who would objectively evaluate research proposals and grants, direct research efforts, and distribute funding. Today, innovation benefactors increasingly fill the seat of the network orchestrator.

At the center of the **Innovation Network** sits a hub firm or "network orchestrator" poised with three responsibilities

- Manage knowledge mobility so information can be easily accessed and fluidly shared across AMC's⁴

- Create network stability to ensure long-term growth and sustainability of the network³

- Ensure that the value created in the AMC's is distributed equitably within the network, perceived as such by the network members,⁵ and protected against leaks to competing networks⁶

► Conflicts with the Future of Scientific Research and National Healthcare

Three main types of conflict exist within the role of the network orchestrator when occupied by an innovation benefactor: financial, scientific, and ethical. First, the financial conflict: when a lab at an AMC receives funding from the NIH, there is no expectation that the lab demonstrate positive research results or generate IP in order to receive funding in the following years because there is no expectation of commercialization from the NIH. Rather, a lab needs to show progress

toward their research aims to continue to receive grants. In contrast, innovation benefactors, acting as the funding body for research, also stand to reap financial benefit if a lab generates IP, thus indirectly placing pressure on labs to show positive results.

The second conflict common to private-sector investment is a scientific one. The interest of the innovation benefactor can place a narrower research aim ahead of scientific interest, potentially missing a broader application of research findings and scientific advancement. Innovation benefactors often create Innovation Networks with the mission of finding a cure for a particular disease or cancer type. Focusing on identifying a single application rather than investigating the broad applicability of a given therapy misses the full potential of therapeutic applications. In fact, the history of medicine is interspersed with examples of serendipitous discoveries applied to different fields. For example, after it originally failed as a diabetes medication, Vinblastine found efficacy in treating lymphoma. Similarly, Rapamycin, originally discovered as an antifungal agent, was found to inhibit the immune response in rats, eventually leading to its application as an anti-rejection medication for organ transplants. Derivatives of Rapamycin are currently being tested for use in cancers.¹⁰

Lastly, an ethical conflict exists for the central hub. Traditionally, NIH committees select research grant proposals, taking into consideration the impact of the research and medical priority. Can the central hub find a self-governance framework that focuses research interests on high impact projects, or will the rise of private funding push research efforts only toward proposals with potential strong returns on investment or particular pet projects of the benefactor?

► A Warning Label

Researchers, physicians, and AMCs should all be warned: be careful from whom you take money. As these issues of conflict remain, it becomes clear that the innovation benefactor cannot also play the role of the network orchestrator. We, the authors, suggest that with the inception of an Innovation Network, an independent oversight board should also be created with the ability to limit the benefactor's role and serve to appoint

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an independent network orchestrator to oversee and manage the Innovation Network. While the transition from public to private-sector funding in healthcare is not, in and of itself, a bad thing, researchers, physicians, and AMCs must remain cognizant of the three issues of conflict that remain standing within the central hub of privately funded Innovation Networks. ■■■

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