



REVIEW

Research resources for tuberculosis at the National Institute of Allergy and Infectious Diseases

NIH, DMID TB program

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SUMMARY

Global control of tuberculosis (TB) requires the participation of multiple stakeholders that cross the spectrum of biomedical research, product development, and implementation and operational research. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), plays a critical role in TB biomedical research and product development by directly supporting and leveraging other funding support strategies and providing research resources to facilitate the translation of knowledge about TB into strategies and tools to more effectively combat disease. The primary mission of NIAID is to support high quality, peer reviewed, investigator initiated research that contributes to innovation in infectious disease research. It is also within the mission of NIAID to assure that research findings are translated into vaccines, diagnostics, and drugs to better prevent, diagnose, and treat this devastating disease.

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1. Introduction

Global control of tuberculosis (TB) requires the participation of multiple stakeholders that cross the spectrum of biomedical research, product development, and implementation and operational research. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), plays a critical role in TB biomedical research and product development by directly supporting and leveraging other funding support strategies and providing research resources to facilitate the translation of knowledge about TB into strategies and tools to more effectively combat disease. The primary mission of NIAID is to support high quality, peer reviewed, investigator initiated research that contributes to innovation in infectious disease research. It is also within the mission of NIAID to assure that research findings are translated into vaccines, diagnostics, and drugs to better prevent, diagnose, and treat this devastating disease.

NIAID is comprised of both intramural and extramural programs that include TB research programs. The **Division of Intramural Research (DIR)** (<http://inside.niaid.nih.gov/organization/dir/Pages/default.aspx#>) conducts basic and clinical research in a wide range of disciplines related to immunology, allergy, and infectious

diseases, including TB, to make scientific discoveries that promote the development of new vaccines, therapeutics, and diagnostics to improve human health. The extramural program supports research conducted by other institutions, including domestic or international academic institutions, industrial partners and small business concerns through grants and contract resources. The extramural program is comprised of three divisions, the **Division of Acquired Immunodeficiency Syndrome (DAIDS)** www.niaid.nih.gov/about/organization/daids/pages/default.aspx, the **Division of Allergy, Immunology and Transplantation (DAIT)** www.niaid.nih.gov/about/organization/dait/Pages/default.aspx and the **Division of Microbiology and Infectious Diseases (DMID)** www.niaid.nih.gov/about/organization/dmid/Pages/default.aspx. Each of these extramural divisions provides resources to the TB research community that is directed to their specific mission within NIAID, through contracts or grants. Some of these resources are dedicated to specific projects, but others provide services that can be accessed by the TB research community.

This summary highlights the various support strategies, available primarily through DMID's extramural TB program, to advance our understanding of TB and fill critical gaps not already addressed by other stakeholders in TB research to further translational

science. A full list of available resources for TB research can be found through the NIAID TB website: www.niaid.nih.gov/topics/tuberculosis/Pages/default.aspx, but this summary will selectively focus on contract resources that are open to TB researchers worldwide to request specific services. Also included are databases that provide TB researchers with both data and data analysis tools for data that are generated by the research community, including data that are generated through many of the other DMID supported resources.

For some infectious diseases with high incidence rates in resource limited settings, as in the case of TB, more support is needed through research funding organizations, to augment participation by the pharmaceutical industry, to develop drugs, vaccines and diagnostics. As a result, multiple stakeholders and funders are working together^{1,2} to fill critical product development gaps for these neglected diseases. These stakeholders and funding organizations contribute to creating innovative interventions and strategies to transform and modernize the tools for curing TB and reducing morbidity and mortality from this treatable disease. To help address this need, DMID supports a wide range of research resources that are focused on advancing candidate drugs, vaccines, and diagnostics through the product development pathway. While these resources are not intended to support an individual intervention all the way from discovery through preclinical and clinical evaluation and, ultimately, to licensure, these services are aimed at helping to lower risks to developers in advancing products and help generate rigorous data that will assist in the selection of the most promising candidates for advanced development.

DMID's TB program leverages strategies within several different categories, listed below, and within each category provides funding opportunities and resources at critical points to provide support across the spectrum of TB research.

2. Funding opportunities to support research

NIAID provides support to the global TB research community for basic science mainly through grant-based programs. Funding support is available through a series of grant mechanisms that are designed to fund early stage research, including studies to generate innovative hypotheses or to evaluate established hypotheses. Investigator initiated research grant applications are submitted in response to "parent" announcements by NIH/NIAID and should be submitted to the funding mechanism most appropriately aligned with the proposed research project design. Choosing which grant mechanism to apply to includes an assessment of the length of time and level of funding needed for the research, the level of risk and innovation involved with the project, and the amount of preliminary data that can be presented in the application. Applicants are encouraged to consult with a Program Officer to obtain feedback on grant mechanisms. Applicants that need to be directed to the most relevant Program Officer for a proposed project can contact the scientific point of contact on a funding opportunity announcement or may search in the NIH RePORTER (www.projectreporter.nih.gov) for similar projects and contact a Program Officer listed in association with a project. Contact information for Program Officers in the NIAID TB programs can be found through the NIAID TB website at: www.niaid.nih.gov/topics/tuberculosis/Pages/Default.aspx.

In addition to these "parent" announcements, NIH/NIAID regularly publishes funding opportunity announcements (FOA) that are focused on specific areas of infectious disease research. Of note is that many of these focused initiatives are not directed to a particular pathogen or disease, but are intended to support research principles that apply to multiple pathogens. Although the FOA may not specifically list or mention TB as a focus area, a large number of

these announcements are open to applications focusing on TB or other mycobacterial diseases. For example, translational research in TB, which often requires collaborations with those working in product development, is eligible for funding under NIAID's Biodefense and Emerging and Re-emerging Infectious Disease research Programs www.niaid.nih.gov/topics/biodefenserelated/biodefense/Pages/default.aspx, as TB is listed as a Biodefense Category C Priority Pathogen. Funding support, particularly through the Biodefense Partnership FOAs, has been heavily utilized by translational TB researchers to advance promising new interventional strategies, research tools, and product candidates. Biodefense funding announcements, including the Biodefense Partnerships, may not specifically list *Mycobacterium tuberculosis* (*Mtb*) in the text of the solicitation but grant applications focused on TB are eligible for any funding announcements that include Category C pathogens.

NIAID/NIH funding mechanisms to support research are described in detail here: www.niaid.nih.gov/researchfunding/grant/Pages/default.aspx.

Current funding announcements can be found at: www.niaid.nih.gov/researchfunding/ann/pages/opps.aspx.

3. Product development services and research tools and technologies

In addition to providing opportunities to obtain research funding through grants, DMID also offers contract-based research resources and product development support services that are accessible free of charge to the research community. Product development services offered through DMID are independent from grants provided through the NIAID extramural programs. They are designed to fill gaps in the product development process, and facilitate the development of diagnostics, vaccines and therapeutics for infectious diseases, including TB, and provide research tools and technologies to contribute to product development. Details for these services can be found at: www.niaid.nih.gov/labsandresources/resources/dmid/Pages/default.aspx. For questions about how to access these services, please contact an DMID Program Officer.

4. Biological research resources (organisms and reagents)

Research reagents derived from mycobacterial pathogens and other related bacteria are available to investigators worldwide through NIAID's reagent repository, **BEI Resources** (www.beiresources.org). Reagents are distributed without cost to investigators who have registered with BEI and assure that appropriate biosafety measures are in place for using these reagents.

Currently, BEI Resources provides close to two thousand *M. tuberculosis* (*Mtb*) specific reagents, as well as reagents derived from other mycobacterial pathogens. These reagents include:

- Gamma irradiated whole cells, cell lysate and cell fractions
- Nucleic acids
- Antibodies and antisera
- Protein reference standards
- Protein expression clones
- Peptide and DNA microarrays
- Knockout and Entry Clone Libraries
- Leprosy research reagents
- Strain collections of lab strains and clinical isolates of mycobacterial pathogens (e.g. H37Rv, H37Ra, HN878, CDC1551, Erdman)

These standardized and quality controlled reagents are intended to facilitate general biomedical research and also encourage

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