

Lovelace Respiratory Research Institute

Legislative Tobacco Settlement Committee

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www.LRRI.org

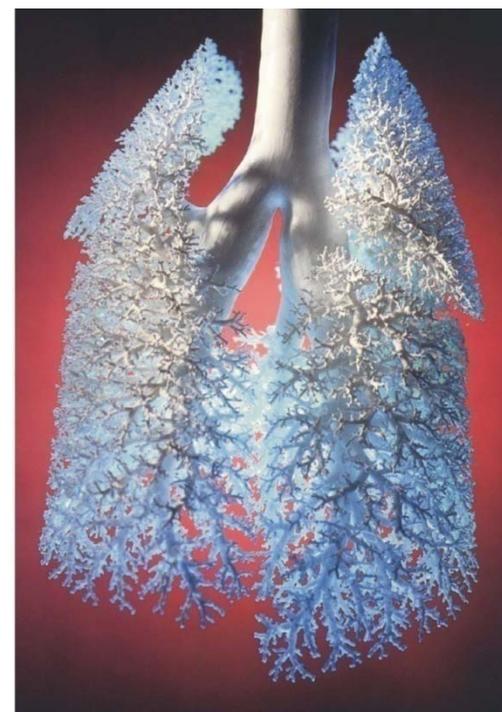


Lovelace Respiratory Research Institute (LRRI)



An independent, private, research institute serving humanity through research on the prevention, treatment, and cure of respiratory disease

LRRI is the only private basic-science, biomedical research organization totally dedicated to the study of respiratory diseases.



Introduction to Proposed NM Drug and Device Development Center



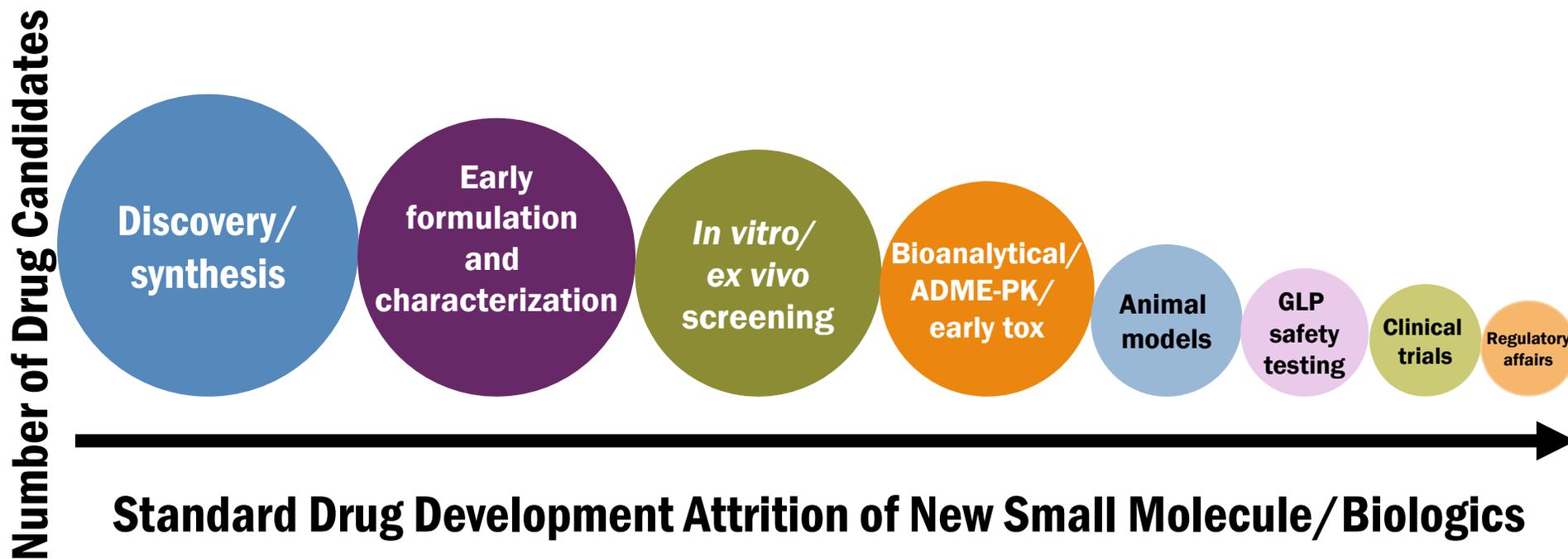
- **Funds that historically have been appropriated to LRRI through the UNMHSC appropriation from the tobacco settlement funds have allowed, over the years, for the creation of this infrastructure at LRRI that now supports over a thousand jobs in New Mexico.**
- **This happens through the leveraging of these technologies to service over 250 commercial clients in the biotechnology and pharmaceutical and device industries. As a stand-alone activity, this legislative support has been a great financial success by any measure.**
- **What is lacking is the ability to close the loop and marry these capabilities with the discovery and clinical trial infrastructure at the UNMHSC that would then keep the discovery in-state and create new companies and high paying jobs here.**



Introduction to Proposed NM Drug and Device Development Center (concluded)

- **This year The Lovelace Respiratory Research Institute has partnered with the UNM Health Sciences Center (UNMHSC) to propose a joint LRRRI/UNMHSC Drug Development Program.**
- **Over the last 10 years the Tobacco Committee has supported LRRRI at \$1M/yr to develop the infrastructure to service the pharmaceutical, biotech, and government R&D activities designed to mitigate the harmful effects of tobacco use.**
- **This has resulted in a high-tech formulation and preclinical facility with trained staff that currently develops over 40 compounds a year.**
- **Literally none of these come from our local New Mexico laboratories.**

LRRI Drug Development



What the Funds Will Support



- **Pay for scientists to design protocols for individual therapies coming out of UNMHSC.**
- **This starts with developing the formulation of the product, and then identifying the Good Manufacturing Practice manufacturer and manufacturing process that will be required to produce research level amounts of the product for the Animal Rule studies.**
- **The funds will then support the lab and technical support to undertake the preclinical studies under the FDA animal rule that requires all drugs be proven safe and efficacious in two species of animals. This is the IND (investigational new drug) application process.**
- **This then leads to an NDA (New Drug Application) application to the FDA to get the product approved for normal human use after testing in people for safety and efficacy.**
- **LRRI will then find the appropriate GMP manufacturer for final production of the product.**

NM Drug and Device Development Center



- **In order for a new medical product to be approved for sale in the U.S., first it must be created (discovery), then formulated to U.S. Food and Drug Administration (FDA) requirements, and then tested for efficacy and safety in two species of animals.**
- **These stages are then followed by testing for safety and efficacy in people. Here in New Mexico we have never married all of these phases of the development process together.**
- **For this reason, new discoveries get moved out of state where they evolve into new companies and new economic activity.**

NM Drug and Device Development Center (continued)



- **As it operates today, a new therapy might be discovered at the UNMHSC but then moved out of state for formulation and animal testing.**
- **The product and the startup company associated with it are thus lost to the state.**

NM Drug and Device Development Center (continued)



- **LRRI and the UNMHSC together possess all of the technology and infrastructure necessary to develop new drugs and devices for medical use.**
- **At the UNMHSC there is a National Institutes of Health (NIH) drug screening center that screens drugs for efficacy in human disease and an NIH-funded Clinical and Translational Science Center that supports the clinical trials necessary to complete moving a product through the FDA process to the clinic.**
- **LRRI has the full complement of Good Laboratory Practice (GLP) preclinical drug development tools including formulation and the two-species animal rule capabilities.**

NM Drug and Device Development Center (concluded)



- **The two organizations have never had the resources to merge these capabilities and offer startup companies the full complement of support necessary and sufficient to create and mature a biotechnology and pharmaceutical company here in New Mexico.**
- **Now the UNMHSC and LRRRI propose to reinstate funding from the tobacco settlement fund at the original level of \$1 million to create the new combined Drug and Device Development Center (DDDC).**