# Translational Research: Role for the Clinical Laboratory Professional?

T. Scott Isbell[1†*]

Given the lack of a precise definition, and aided by a fluidity of application whereby observations made at the bench are "translated" to the bedside and vice versa, many can claim to conduct translational research. To quote Dr. Steven Woolf in a 2008 commentary published in the *Journal of the American Medical Association*, "Translational research means different things to different people, but it seems important to almost everyone" *(1)*. In the early 2000s, the Institute of Medicine's Clinical Research Roundtable classified translational research into 2 major blocks. T1 is defined as "the transfer of new understandings of disease mechanisms gained in the laboratory into the development of new methods for diagnosis, therapy, and prevention and their first testing in humans," and T2 is "the translation of results from clinical studies into everyday clinical practice and health decision making" *(2)*. Within academic medical centers, the T1 block has received most of the attention.

In a 2015 article published in *Science Translational Medicine*, Professor Hans-Dieter Volk and colleagues *(3)* argue that academia should take a more active role in translational research, specifically by providing more leadership in the identification and preclinical validation of basic science observations. They present a framework for advancing academic translational research based on discussions at a Berlin conference, *Translate 2014!*, and call for the creation of essential infrastructure, the identification of necessary expertise, and the securing of resources needed to translate observations made at the bench all the way to clinical proof of mechanism (PoM)[2] and proof of concept (PoC).

Volk and colleagues discuss the framework for efficient translation of basic research observations around 3 major steps in the process: Step 1: selecting translational projects; Step 2: conducting clinically relevant in vitro and in vivo studies, such as preclinical PoC; and Step 3: conducting clinical PoM and PoC trials.

The clinical laboratory professional (e.g., the PhD clinical scientist or MD/DO clinical pathologist) is well positioned to provide leadership in translational research. Expertise in the principles of good laboratory practices, access to patient specimens, and an appreciation for regulatory standards make the clinical laboratory professional well suited to provide consultation and/or oversight of preclinical studies aimed at the validation of observations made at the bench in patient-derived specimens (blood, urine, biopsies, etc.). Moreover, access to clinical data allows for the required clinical and pathologic correlations to be performed.

The clinical laboratory professional may also play an important role in biomarker studies typical of early clinical trials, in which identification of biomarkers for monitoring safety, responsiveness, efficacy, and patient stratification and prognosis are essential. Here, combined knowledge of pathophysiology and measurement science provides the clinical laboratory scientist with an advantage.

This *Science Translational Medicine* article should serve as a call for clinical laboratory scientists and pathologists to reflect on their role in the process of translational research. There are certainly opportunities for us in this sphere, and it is our responsibility to leave the laboratory and assert ourselves in the process.

[1] Department of Pathology, Saint Louis University School of Medicine, St. Louis, MO.
[†] Member of the Society for Young Clinical Laboratorians (SYCL) (http://www.aacc.org/community/sycl).
* Address correspondence to the author at: Department of Pathology, Saint Louis University School of Medicine, 1402 South Grand Blvd, St. Louis MO 63104. E-mail isbellts@slu.edu.
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[2] Nonstandard abbreviations: PoM, proof of mechanism; PoC, proof of concept.

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