

Bob Barrett: This is the podcast from '*Clinical Chemistry*'. I am Bob Barrett. Although biomarker research continues to grow, there has been a relative lack of new laboratory-based tests raising important questions about translating basic research into clinical diagnostics.

Is the lack of clinical results from biomarker discoveries a result of exhausting current biomarkers or is it a sign of the limitations of new markers? Since all potential protein markers have not been characterized, attention has turned to the biomarker pipeline that should also be providing clinical utility to these markers.

In a prospective published in the January 2012 issue of '*Clinical Chemistry*', Dr. Leigh Anderson, the Founder and CEO of the Plasma Proteome Institute in Washington D.C., analyzed these recent approaches and has some encouraging findings.

Dr. Anderson is our guest in this podcast. Dr., just what is a biomarker pipeline?

Dr. Leigh Anderson: Biomarker pipeline is a concept of the process that's required to translate some basic discovery about the association of a protein, for example, with a clinical state, either something that could actually be used in the clinical lab. So it comprises the steps that are usually thought of in a pharmaceutical pipeline.

For example, from basic discovery, in this case of a biomarker, through the verification step in which large numbers of clinical samples are used to establish clinical utility, and then through development and ultimately into a form of a clinical test that can be used in the clinical laboratory or ultimately approved by the FDA. So it's a long process from real discovery all the way through the clinical laboratory.

Bob Barrett: And how do these papers contribute to demonstrating a functional biomarker pipeline?

Dr. Leigh Anderson: Well, these papers represent a real advance in the sense that they have extended what the proteomics community and biomarker community can do from this basic discovery of candidate biomarkers through the initial steps of doing the verification to weed out those few that really work in the clinically significant number of samples.

And most previous investigations, in fact almost all previous work, with just a few exceptions in biomarker proteomics, has really stopped short with the publication of a set of candidate biomarkers. And I believe we now understand that the success rate of biomarkers, published biomarkers,

when they are applied to real clinical samples in large sets is very low, and therefore this verification stage, which has been added to the discovery in these two publications, represents a real step forward.

Bob Barrett: What does a complete biomarker study cost?

Dr. Leigh Anderson: Well, that's unfortunately the not so good news is that it's expensive to do this, and that's because the discovery effort is significantly expensive to look at large numbers of proteins. In this case a 1,000-2,000 proteins were measured in the samples from which the discovery was done and then to develop some specific assays to do the verification testing in large sample sets.

And at the end of the pipe it looks as if it's going to cost something on the order of \$4 million and probably take about four years to do studies of the scale and quality of these two publications.

Bob Barrett: So are we close to seeing major biomarker breakthroughs?

Dr. Leigh Anderson: Well, you can't claim success until you see it and it has been replicated, but it looks much closer than it has looked for some time. These studies look as if there are real biomarkers that have been discovered in each of these two cases, although we will wait to see the real clinical applications before we can know for sure.

But it does look now as if the understanding is there, and the technology is there to produce real biomarkers in a range of diseases. And so I think the level of optimism in this field has significantly increased in the last couple of years, and for very good reasons.

Bob Barrett: Dr. Leigh Anderson is the Founder and CEO of the Plasma Proteome Institute in Washington D.C. He has been our guest in this podcast from *'Clinical Chemistry*.

I am Bob Barrett. Thanks for listening!

Total Duration: 4 Minutes