Diaceutics

Expert Insight

Mystery Solved! What is the Cost to Develop and Launch a Diagnostic?

By: Dr. Doug Dolginow, Dr. Katherine Tynan, Noel Doheny and Peter Keeling

Diaceutics asked four senior executives in the pharma and diagnostic industry to come up with a value on how much it would cost to launch and commercialize a novel diagnostic test. Here's what they came up with.

Every other year Diaceutics holds a convergence meeting in Washington DC composed of some 35 invited movers and shakers in the personalized medicine world, split pretty much 50:50 between diagnostic and pharma companies. Always a forum for great debate and networking, this year's meeting focused on how to cooperate in the commercialization of non companion diagnostics. However at this year's meeting [2013], there was a collective gasp of disbelief among the pharma audience when I put up a number on the screen suggesting that on average the cost of developing and commercializing a diagnostic properly in the US is $50 million to $75 million.

This is not the first time I have met with disbelief when talking about the cost of commercializing a diagnostic and clearly others have met with the same reaction. We decided then to open this number up to external scrutiny, in short to get a few 'people who have actually taken a test from soup to success' to give their view and once and for all get the dollar facts out there. In total, a virtual expert panel of four senior folk in the industry (names below) were asked to come up with agreement on the investment required to truly commercialize a novel test.

Costs were broken into two buckets: development to launch, and launch and commercialization costs. In general, it was agreed that there is more accurately a dollar range, depending upon the novelty of the technology being developed. We defined low end as a follow on diagnostic product where a similar test exists in the market, and a high end test which is a new biomarker (needing to establish novel clinical utility), or a new platform likely to be in oncology, a chronic disease like rheumatoid arthritis or a range of infectious markers requiring panel performance. The dollar range ran from $20 million to $106 million and is detailed in Table 1.

All numbers are in US$m	**Low end**	**High end**
Development and Manufacturing Costs		
Technology acquisition and protection	0.6	4.0
QSR and FDA compliance	1.0	3.0
GMP manufacturing	0.5	5.0
Platform development (buy in or make)	3.0	20.0
R&D (based on 1-3 years of FTEs at 200k/yr loaded spend)	3.0	8.0
Clinical utility trials retrospective versus prospective	1.0	10.0
Admin and financing	3.0	5.0
Subtotal costs to launch	12.1	55.0
Sales and Marketing Costs (US market only)		
Direct sales team (assuming required for 3 years)	3.0	12.0
Health technology assessment and payer negotiations	1.0	4.0
Clinical education (guidelines – KOL endorsement multi-stakeholder education)	2.0	25.0
Marketing (launch meetings, representative detail aids, online marketing)	2.0	10.0
Subtotal costs to drive adoption	8.0	51.0
Total costs to commercialize	**20.1m**	**106.0m**

Table 1. Dx Development and Commercialization Costs.

Key:
Low end = follow on product, existing owned platform, infectious disease

High end = new assay, new platform, new technology, oncology or chronic disease

The expert panel was then asked to provide comment on these costs. These are summarized below:

- The elements in Table 1 are equally important as the absolute values. Every execution will have a different mix of costs in its path to market.
- The costs really start to rack up when you are developing a new assay system that enables you to change the location of testing (even for existing analytes) OR when you are developing new analytes without established clinical utility.
- Changing current clinical practice (a new site of use, a new lab user or a new caregiver) is the most challenging thing that diagnostic companies have to do and is the most expensive. Anytime you need to develop evidence to support the deployment of a new test or system, it is expensive. The perverse incentives in our current US 'procedure driven' medical system apply just as much to diagnostics as other areas of medicine. Getting a pathologist to switch from an IHC test where he/she makes money to a more sensitive/specific molecular test requiring evidence of more than analytical/clinical validity. In essence, you have to 'follow the money', understand each stakeholder's perspective and map out the evidence requirements for each.
- It is interesting that many diagnostic methods and platforms have emerged, been implemented and have dramatically changed care. A few examples include diabetes self monitoring, therapeutic drug monitoring, hormone management, blood viral detection, viral genotyping and tumor analysis. The key missing element has been the documentation of the impact of these game changers. The ultra competitive diagnostic landscape lacks a 'success library' or a meaningful trade association that brings the data together. And the payers remain to a great extent oblivious to the impact of these developments.
- Development-only costs of simpler platforms:
  - Point of care assays with simple readers and with established analytes can potentially be developed for ~$15 million. At the end of the day, simple means lab-like for use in new environments and puts more of the onus on the developer to configure production and performance protocols that reduce downside end user risk.
  - Menu expansion assays on existing platforms for something like an IHC/immunoassay/PCR test for a CDx program could probably be done for ~$10 million to $15 million where you have existing distribution channels in place.
  - However, developing a new platform and menu can be over $100 million.
- Despite the cost estimates above, many diagnostic companies underfund the development of their market largely due to tight fiscal management versus return. It is much simpler/easier to fund the next analyte on an introduced platform than to invest in a game changing assay or format. And the next new method may pull more platform sales through for the developer.
- In companion diagnostics, however, speed to market development is of the essence and pharmaceutical companies in general require rapid and total development of the companion diagnostic market versus the gradual horizons of many diagnostic companies. Thus the spends to move the market from one of test avoidance to test adoption are likely to be at the high end and require earlier, even pre-launch investment in market development.
- On the importance of the right investment in health technology assessment:
  - In general very few people understand the archaic, expensive and time consuming process that is reimbursement – this includes coding, pricing and coverage. The current practices emerged over a thirty-plus year window which saw reward , regulation and technology undergo massive change. With average technology lifecycles of 8 to 12 years in leading edge fields, some tests have gone through three generations without any change in the payment mechanism. The perhaps unfortunate reality is that CPT coding makes test volumes visible and therefore responsible for driving cost increase.
  - The level of scrutiny the payers are applying to this area is disproportionate to the spend but they see advances in molecular diagnostics in particular as driving increased utilization in general. Therefore, the onus is on sponsors to provide better cost utilization and health technology assessment data than was the case in the past. There is almost a reverse incentive mechanism pushing the onus for cost control onto diagnostics (2.5 per cent of US health care spend) rather than on the patient care providers who get a majority of the payment.
  - One challenge in this space is the inability to study the cost impact until post approval windows. It is not appropriate to use any diagnostic method result during a review cycle pre-clearance or approval. Just a bit of a conundrum: you need cost-effectiveness data in advance of uptake and it is not possible to generate unlike in pharma, where prospective trials allow/mandate use of the compound in the trial phase. Very few diseases have been so completely modelled that providers and payers will accept modelling to drive their decisions.

So there you have it: the cost to develop and commercialize a diagnostic is subject to a considerable investment range, depending on the test positioning and novelty. On average, an additional investment of about $50 million to commercialize a diagnostic should be factored in to the additional cost of targeted therapy if the test is to contribute to enabling the right patient to be treated at the right time.

My thanks to our expert panel for this cost assessment and analysis.

Biographies
Dr. Doug Dolginow has extensive experience in the personalized medicine arena and has served as CEO, COO and on the Board of Directors of several organizations focused on furthering the reach of personalized medicine. Prior to joining the Ignite Institute, Dr. Dolginow served as CEO of NanoValent Pharmaceuticals. Dr. Dolginow also co-founded and served as CEO of Calderome, Inc., which led to the founding of Veracyte, an early stage cancer diagnostics company addressing the emerging opportunities in personalized medicine. Dr. Dolginow co-founded and served as President and COO for OncorMed which he took public in 1994 and sold to Gene Logic in 1998, where he then served as Executive Vice President of Pharmacogenomics.

Dr. Katherine Tynan is a seasoned biotechnology entrepreneur with a focus on business development, startup entrepreneurship, fundraising and strategic business planning for clinical diagnostic companies. She has a background in reimbursement, financial analysis, operations, product development, diagnostic reimbursement and commercialization of new technologies for clinical diagnostics. In her current role as a consultant, Katherine works with a number of early stage and established multinational diagnostic companies, guiding them through product development choices, market entry strategies, funding ($21 million raised) and a diverse range of business development transactions.

Noel Doheny, CEO of Epigenomics, has 30 plus years of experience in the field of diagnostics, with over 20 years in senior management. In his most recent position as CEO of OpGen (2008 to 2009), Mr. Doheny led the transformation of an incubator lab services company into a systems company in less than two years. Prior to this, he held positions as Senior Vice President for the Molecular Diagnostics Division of Affymetrix Inc., Vice President of Pre-Analytical Solutions and was a member of the Executive Committee at QIAGEN, as well as President and CEO of BioStar Inc. (known as ThermoBioStar post-acquisition). Importantly for Epigenomics as it continues to build a US sales force, he has built several operating teams from the ground up, including the commercial teams to launch novel products at companies such as Ciba Corning, ThermoBiostar and OpGen. Mr. Doheny obtained degrees in Biology and Chemistry from West Virginia University and attended Georgetown University for postgraduate studies in Biochemistry prior to moving into industry.

Peter Keeling, CEO of Diaceutics, brings over twenty-four years of experience in international health care, having directly initiated and managed the launch of four pharmaceutical, seven OTC and five diagnostic products, in addition to three joint ventures and two major joint corporate marketing campaigns. In addition to Peter's extensive operational experience in the US, he also has substantial experience running operations in all the key health care markets of the world, including Germany, the UK and Japan. Peter has spent two extended periods in applied industrial research, including a year at MIT's Pharmaceutical Program at the Sloan School of Management in Boston.