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THE GLOBAL MARKET FOR NEXT-GENERATION SEQUENCING TESTS CONTINUES ITS TORRID PACE

by Kathryn A. Phillips, PhD and Michael P. Douglas, MS

The market for next-generation sequencing technologies (NGS) has grown dramatically since the technology was first commercialized, but it's important to quantify that growth and describe future trends. We provide a snapshot of market trends using market trend analyses and equity research reports focusing on NGS. The NGS market is growing rapidly and is expected to continue its torrid pace. However, there are significant challenges that may dampen future growth if not addressed.

The market trend analyses were published in 2016-2017.[1-3] We also obtained relevant equity research reports from Morgan Stanley (N=9).[4-12] The market trend analyses report empirical forecasts and describe factors related to growth rates, while the equity research reports are more descriptive in nature and incorporate expert opinions from interviews and other sources. Both types of reports stated they used primary data, including soliciting assessments from NGS experts, as well as publicly available data sources, although specific analytical methods are proprietary and thus not reported (reports were obtained through an agreement with the University of California and through personal communications).

Defining NGS Products and Clinical Markets

The NGS products market as a whole is categorized by specific uses (clinical, research, and agricultural) and products (instruments, consumables, bioinformatics, and services). We focus particularly on clinical NGS services. **Figure 1** shows the size of markets and indicates how "markets" are defined. Results are reported using the compound annual growth rate ("CAGR"), a measure of growth over multiple time periods that takes into account compounding over the time-period.

Worldwide Market Size of NGS Products and Services

The market size for NGS products is growing. This market was nearly $5.9 billion in 2015 and is forecast to reach $13.8 billion by 2020 (18.7% CAGR).[2] A substantial and growing component of this market is represented byNGS services provided by companies that provide either raw data or a report to users. The total NGS services market was nearly $2.9 billion in 2015 and is forecast to reach $9.1 billion by 2020 (26.0% CAGR).[2] One key

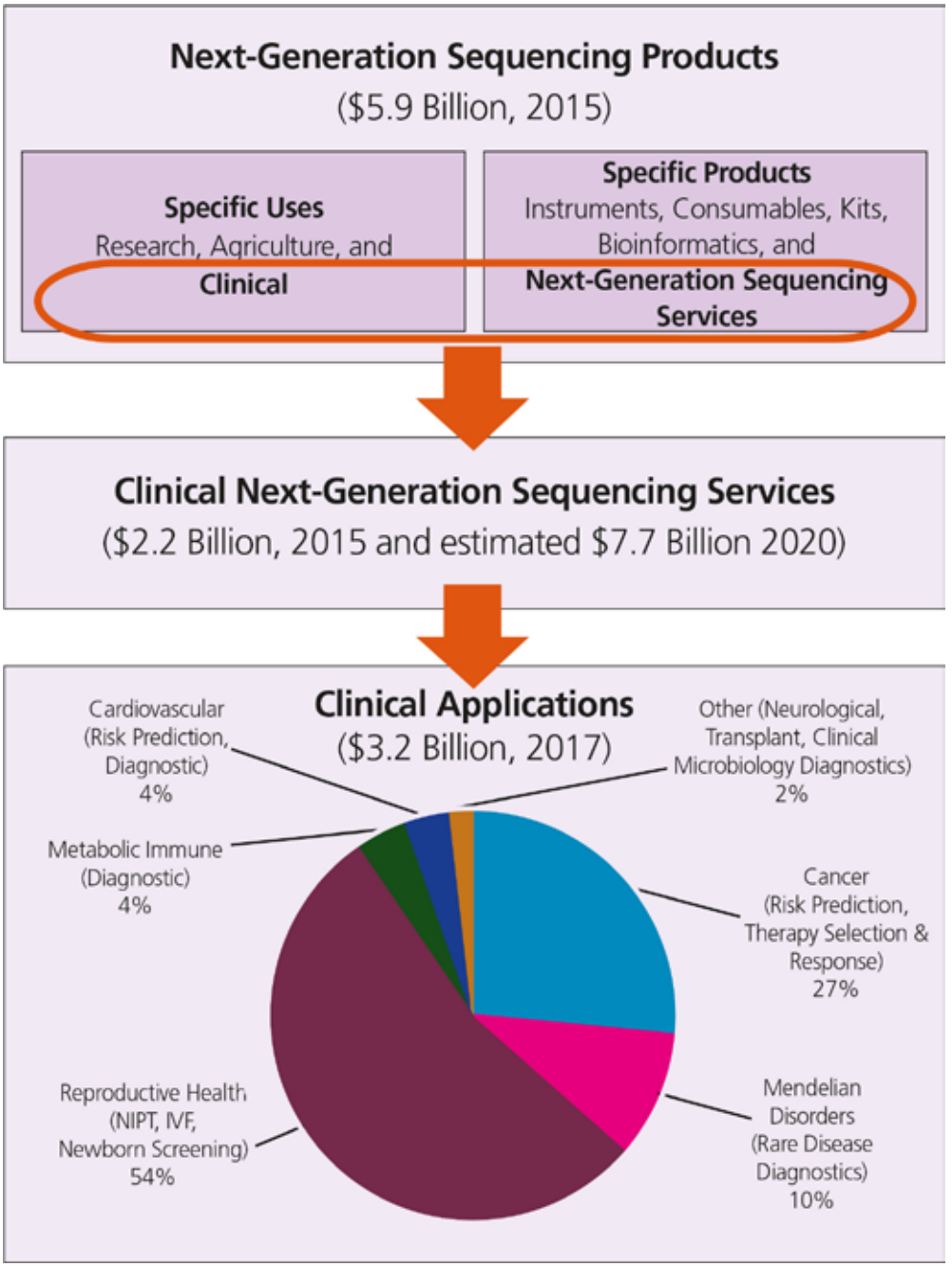

Figure 1: Market Size for NGS Sequencing Products, Clinical NGS Services, and Clinical NGS Applications

SOURCE [Authors' original figure, authors' interpretation of data from Bergin J. 2016. DNA Sequencing: Emerging Technologies and Applications, and Bergin J. 2017. Next-Generation Sequencing: Emerging Clinical Applications and Global Markets.]

trend is the transition from the use of Sanger-based sequencing to NGS sequencing, with an expected decrease in the market for Sanger-based instruments and consumables of almost 5% CAGR by 2020.[2]

Worldwide Market Size of Clinical NGS Services

Clinical NGS services is the fastest growing component of the overall NGS market (**Figure 1**). It encompasses diagnostics, risk prediction in cancer and other diseases (e.g. cardiovascular), therapy selection and monitoring, and screening. The global clinical NGS services market was $2.2 billion in 2015 (37% of the total market) and is forecast to reach $7.7 billion by 2020 (28.1% CAGR).[2]

Worldwide Market Size of Clinical NGS by Application

NGS tests are used for a variety of clinical applications worldwide (**Figure 1**).

The reproductive health NGS test market is the largest market (54%) at $1.7 billion in 2017, and is expected to reach $3.3 billion by 2022 (13.8% CAGR).[3] This consists of NIPT (the largest category), carrier screening, in vitro fertilization, and newborn screening.[3]

The oncology NGS test market makes up the second largest market (27%) at $838.8 million in 2017, and is forecast to reach $4.1 billion by 2022 (37.3% CAGR).[3] Other applications include Mendelian (rare) disorders, complex diseases, and transplant diagnostics.[3]

Clinical applications can be further segmented by whether they are considered "current" or "emerging" markets. Current markets include cancer, HLA typing (for transplants), Mendelian disorders, metabolic and immune disorders, prenatal testing, and IVF. Emerging markets include cardiovascular, food-borne illness, neurological, and newborn screening.[3]

Worldwide Market Size of Clinical NGS by Type of Test

The global clinical NGS market can also be segmented by the type of test. The largest market is for tests that sequence 50 genes but not the entire exome or genome. This market is estimated to be almost $2.6 billion in 2017 and forecast to reach $5.2 billion in 2022 (15.3% CAGR).[3] However, the markets for whole exome and genome sequencing tests are rapidly increasing from their small base. The exome sequencing market is estimated at $152.2 million in 2017 and is forecast to reach a size of $1.3 billion in 2022 (53.9% CAGR), while the whole genome sequencing market is estimated at $32.9 million in 2017 but expected to reach $1.0 billion in 2022 (98.8% CAGR).[3]

North American NGS Clinical Market

A significant portion of the NGS clinical market is based in North America (United States, Canada, and Mexico) which accounted for 43.7% ($1.3 billion) of the global clinical market in 2017. However, this percentage is forecast to decrease to 35% ($3.6 billion) in 2022. While this region's market is growing at an overall CAGR of 22.2% during this period, the rest of the world is growing at a faster rate.[3] One reason is the growth of markets in Asia, especially China as well as India.[3] Another reason is that some experts believe that early cancer detection assays (e.g. liquid biopsy) will ramp up faster outside the US.[4]

Factors Contributing to Greater Use of NGS and Future Growth

The combination of unmet clinical needs for better tools to predict, diagnose, treat, and monitor disease and increasingly efficient sequencing technologies are major factors driving the growth of NGS.[1-12] Other factors driving growth include the increased understanding of the molecular basis of disease, patient demand, industry investment, and regulations that allow marketing of tests without FDA approval.

However, within this overall growth there are important variations. For example, some experts believe that, within oncology, smaller, targeted panels will take market share away from large panels that measure hundreds of genes.[7]

Key Challenges to Be Addressed for NGS Markets

Despite rapid NGS test growth, there are a number of key issues that will need to be addressed to facilitate future growth. The still relatively high total costs of delivering NGS test results compared with other technology platforms, and limited coverage by payers, are key challenges. NGS remains relatively costly requiring initial equipment investment, specialized workforce requirements, and time-intensive variant interpretation. Our previous work has found limited and variable coverage of NGS tests by payers,[13-18] but the recent Centers for Medicare and Medicaid national coverage determination on Medicare coverage for tumor sequencing may portend increased coverage.[19,20] Other challenges include the need to define and document clinical utility in peer-reviewed publications and the need for laboratory markets and regulatory processes to evolve with testing. There are also concerns that patients may face high out-of-pocket costs, while current patient assistance programs that cover these programs may be unsustainable. There is a need for clinical guidelines and consensus documents that provide evidence-based recommendations regarding test use in clinical practice.

Summary

In summary, the NGS market is growing rapidly and is expected to continue its torrid pace. However, there are significant challenges that may dampen future growth if not addressed. ■

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