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Figure 1. Sixty-eight companies were identified as producing hardware, software, reagents and services for use in the clinical NGS pipeline. Each horizontal row represents one company, categorized in the columns by the products and services the company offers. Thirty-one light colored companies are either involved in sequencing only (10) or annotation and interpretation only (21).

Supplementary Materials

Supplementary methods:

Interviews with industry leaders

We conducted semi-structured in-depth interviews with industry leaders (n=19) to identify main policy concerns and trends in how companies are strategically positioning themselves within the industry. We identified major companies involved in several sectors of the clinical NGS industry, including manufacturers of hardware and reagents, developers of analytic software to align, analyze, annotate and manage large data files, and directors of commercial and academic laboratories. The CEOs or clinical directors of these companies were contacted through email and invited to participate in an interview

(n=27). Three actively declined, nineteen participated, two expressed interest but did not respond to follow-ups, and four did not respond. After obtaining verbal informed consent, telephone interviews were conducted using a semi-structured interview guide developed by the study team. Average interview length was 57 minutes. Interviewees came from hardware and reagent manufacturers (4), clinical laboratories performing NGS (5), informatics companies (6), clinical Next-gen test manufacturers (3) and one professional association. Each interview was audio recorded with permission, transcribed, de-identified and analyzed for thematic content related to policy uncertainty and industry development. The Institutional Review Boards at John's Hopkins University and Baylor College of Medicine approved all study materials and methods.

Web-based Search

A comprehensive web-based search was conducted to confirm trends identified by interview participants. Companies were identified through CrunchBase and PubMed searches, genetics blogs and daily bulletins, and Google alerts including the key phrases: "next generation sequencing," "whole genome sequencing," "personalized medicine," and "genomic testing." Companies were also identified by attending industry events, such as the Personalized Medicine World Conference, the Clinical Genome Conference, the Consumer Genetics Conference, and annual meetings of the American Society of Human Genetics and the American College of Genetics. From September 2012 to December 2013, 116 companies were identified online. Companies based solely outside the US or not subject to US regulation (n=10) and those that went bankrupt over the course of our study (n=1) were excluded. Acquired companies (n=5) were also removed from our list,

but were tracked carefully by transferring the collected information from bought companies to acquiring company.

The remaining 100 companies offered a range of services from technology providers to analytic software developers. The websites and publicly available information of these companies were reviewed to establish their services and customer base. We recorded where on the NGS pipeline each company was operating, and whether they had any certifications and privacy, data storage, or reimbursement policies. These data were cross-referenced with industry-related market reports and when possible confirmed by speaking directly with company representatives.

To determine how many of the companies were operating in the clinical NGS space we first looked at the companies' practices and services to determine if they were working directly with clinicians, had clinical advisors, staffed genetic counselors, and produced clinical reports. Other criteria that indicated company practices and services would need to meet standards for clinical use included CLIA certification, Sanger confirmation of samples, and laboratory information management systems (LIMs). Additionally, we tracked whether these companies were seeking reimbursement and developing software to integrate genomic information into electronic medical records. Based on these criteria, 68 companies were determined to be operating in the clinical NGS space.

Supplementary Table [in Excel]