The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on patient access and the innovation ecosystem

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Supplemental Data

Figure S1. Survey Design. The survey was designed to select for innovator and healthcare investors with experience in reimbursement for health technology.



Figure 2. Demographics of innovators. A. The majority of respondents were executive leaders or reimbursement-focused professionals. B. The majority of respondents worked for companies with 500 or fewer employees. Note that companies with 1 to 50 employees may also be mature companies. C. Respondents were highly experienced with an average of 22 (+/- 9.7) years of industry experience. D. Respondents had experience in multiple clinical areas with an average of 3.2 (+/- 2.3) clinical areas each. Respondents selected from a list of 8 clinical areas and could provide additional clinical areas through an Other option. The number of clinical areas is derived from the total number of clinical areas declared by each respondent including clinical areas added in the Other category.

A. Primary role in healthtech development



B. Employer Size



C. Years of Experience



D. Respondents with specific clinical area expertise





Innovators	N=253	
Role	Number of Respondents	Percent of Total Respondents
Executive Leadership	151	60%
Reimbursement / Market Access	61	24%
Research and Development	13	5%
Clinical Affairs	9	4%
Manufacturing and Quality	2	1%
Regulatory Affairs	3	1%
Commercial or Strategic Marketing	13	5%
Sales / Sales Operations	1	0.4%
Organization Size		
Large Company (>10,000 employees)	30	12%
Mid-size Company (500 to 10,000 employees)	26	10%
Small Company (50 to 500 employees)	53	21%
Start-up (1 to 50 employees)	127	50%
Consultancy or Individual Innovator	17	7%
Years of Experience		
Less than 5 years	7	3%
5 to 10 years	28	11%
11 to 20 years	99	39%
21 to 30 years	79	31%
31 to 40 years	33	13%
More than 40 years	5	2%
Primary Experience in Medical Device or Diagnostics	233	92%
Clinical Areas of Expertise		
Cardiovascular Disease	165	65%
Other	97	38%
Oncology / Cancer	84	33%
Orthopedics	81	32%
Neurological Disease	75	30%
Neurovascular Disease / Stroke	71	28%
Pulmonary Disease	67	26%
Endocrinology / Diabetes	59	23%
Metabolic Disease / Obesity	43	17%
Pediatric Diseases	34	13%
Respondents Working on a Product Seeking or Granted FDA Breakthrough Product designation	193	76%
Self-Assessed Expertise in Reimbursement		1
Modest (3 to 5)	46	18%
Mid-level (6 to 8)	134	53%
Expert (9 or 10)	71	28%

Table S1. Demographics of innovators

Figure S3. Demographics of healthcare investors. A. The size of the fund dedicated to healthcare varied enormously with about half of the investors deploying between \$100MM and \$500 MM. B. 41% of investors *specialize* in medical device or diagnostics investing (eg: over half of their total investments are in this area). C. Respondents reflect a varied viewpoint on investing in companies with or pursuing breakthrough designation for their products. The majority have invested in three to five companies of this type.



A. Investments dedicated to healthcare

B. Healthcare investments dedicated to medical device or diagnostic products



C. Number of investments in companies pursuing breakthrough designation



Table S2. Demographics of healthcare investors

Healthcare Investors	N= 83	
Investments Dedicated to Healthcare Investing	Dollars (\$, MM)	
Average	\$ 1,423	MM
Median	\$ 150	MM
Investments Dedicated to Healthcare Investing	Number of respondents	Percent of total respondents
Less than \$20 MM	8	10%
\$20 MM up to \$100 MM	13	16%
\$100MM up to \$500 MM	46	55%
\$500 MM up to \$2,000 MM	12	14%
\$2,000 MM or more	4	5%
Percentage of Healthcare Investments Dedicated to Medical Device and Diagnostics		
None	2	2%
Minimal Investment (<10%)	4	5%
Minority of Investments (11% - 50%)	43	52%
Majority of Investments (51% to 75%)	10	12%
Predominant Investment (>75%)	13	16%
Exclusive Investment (100%)	11	13%
Self-Assessed Expertise in Reimbursement		
Modest (3 to 5)	14	17%
Mid-level (6 to 8)	55	66%
Expert (9 or 10)	14	17%

Figure S4. The importance of external risk factors to an investor's decision to invest or not invest in a healthcare company. Respondents were asked to rank order the impact of external risks on their investment decisions. The composite score is the average of point scores assigned to each rank (Rank 1 = 6 points, Rank 2 = 5 points, etc). The composite score indicates that the reimbursement pathway has the highest impact among external risk factors when investors are evaluating a potential investment.





Figure S5. Perceptions of the current reimbursement pathways for novel and breakthrough devices. Both innovator and investor respondents were asked to respond to the question "Do you agree or disagree with the following statement? The existing parallel review process with FDA and the CED pathway are sufficient to provide timely patient access for novel medical technologies." Both groups do not agree that the pathways are sufficiently supporting breakthrough innovations.

Perceptions of whether the existing parallel review and CED pathways are sufficient to provide timely patient access to novel medical technologies (% of respondents, Innovators N=253, Investors N=83)



Figure S6. Innovators answered the question: "How likely would you, personally, be to work on a novel or breakthrough product in one of the following areas as your next product if there was a new accelerated pathway for such products and you were required to collect and report real world evidence about the product for 4 years after FDA authorization?" Those that had experience in the clinical area (see Figure S2D) AND answered "Highly likely" or "somewhat likely" were compared to the total pool of innovators in the survey.



Figure S7. Investors were asked, "If a new program that expedites Medicare patient access by immediately granting Medicare coverage upon FDA authorization were established, how would your investment in early-stage companies developing novel or breakthrough medical technology for the following disease states change?" Overall, investors indicated that they would increase their investing in companies developing novel and breakthrough technology.

How would your investment in early stage companies change with an program that expedites Medicare patient access?



(% of respondents who would increase investment, N=83)

Table S3. Patient impact calculations for each featured brea	akthrough technology.
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Featured Breakthrough Technology	Impact Calculations
Reducing Bleeding Complications in Cardiothoracic Surgery	50,000 patients undergo emergency cardiac surgeries annually x 65% experience life-threatening bleeding events x 40% reduction in circulating ticagrelor levels = reduction of 13,000 major bleeding events
Early Diagnosis of Skin Cancer	No calculations
Reduction of Hypertension	190,000 deaths (primary cause) x 13% reduction due to 10 mmHg blood pressure decrease x 66% responder rate to technology = 16,300 lives saved
Early Diagnosis of Pancreatic Cancer	1,000,000 newly-onset diabetes cases annually X 1% of new diabetic patients proceed to pancreatic cancer diagnosis X 56% technology sensitivity (at 99% specificity) = 5,600 to 10,000 cases caught early