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

## Primary role in healthtech development

(\% of respondents, $\mathrm{N}=253$ )


- Executive Leadership
- Reimbursement / Market Access
- Research and Development
- Commercial or Strategic Marketing
- Clinical Affairs
- Other


## B. Employer Size

## Employer size

(\% of respondents, $\mathrm{N}=253$ )


## C. Years of Experience

Years of experience
(\% of respondents, $\mathrm{N}=253$ )

D. Respondents with specific clinical area expertise

Respondents with specific clinical area expertise
(\% of total respondents, $\mathrm{N}=253$ )


Table S1. Demographics of innovators

| Innovators | $\mathrm{N}=253$ |  |
| :---: | :---: | :---: |
| 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 |  |  |
| Modest (3 to 5) | 46 | 18\% |
| Mid-level (6 to 8) | 134 | 53\% |
| Expert (9 or 10) | 71 | 28\% |

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 $\$ 500 \mathrm{MM}$. 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

Investments dedicated to healthcare
(\% of respondents, $\mathrm{N}=83$ )

B. Healthcare investments dedicated to medical device or diagnostic products

Healthcare investments dedicated to medical device or diagnostic products
(\% of respondents, $\mathrm{N}=83$ )

C. Number of investments in companies pursuing breakthrough designation

Number of investments in companies pursuing breakthrough designation
(\% of respondents, $\mathrm{N}=79$ )


Table S2. Demographics of healthcare investors

| Healthcare Investors | $\mathrm{N}=83$ |  |
| :---: | :---: | :---: |
| Investments Dedicated to Healthcare Investing | Dollars (\$, MM |  |
| Average | \$ 1 | MM |
| Median | \$ | 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.

Importance of external factors on the decision to invest or not invest in a healthcare company
(Composite score, $\mathrm{N}=83$ )


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 $\mathrm{N}=253$, Investors $\mathrm{N}=83$ )


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.

Innovators experienced and likely to develop novel and breakthrough products in specific clinical areas (\% of respondents, $\mathrm{N}=253$ )


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, $\mathrm{N}=83$ )


Table S3. Patient impact calculations for each featured breakthrough technology.

| Featured Breakthrough Technology | Impact Calculations |
| :---: | :---: |
| Reducing Bleeding Complications in Cardiothoracic Surgery | 50,000 patients undergo emergency cardiac surgeries annually $65 \%$ 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 <br> $1 \%$ of new diabetic patients proceed to pancreatic cancer diagnosis x $56 \%$ technology sensitivity (at $99 \%$ specificity) = <br> 5,600 to 10,000 cases caught early |

