NVCA-AdvaMed-MDMA Medicare Coverage for Innovative Technology Survey

The Centers for Medicare & Medicaid Services (CMS) issued the final rule for the Medicare Coverage for Innovative Technology (MCIT) pathway proposal in January 2021. Originally intended to go into effect March 15 but now on hold pending a second comment period, the rule would establish a new MCIT pathway to provide four years of national Medicare coverage as early as the same day as market authorization for FDA-designated breakthrough devices. The MCIT pathway is a meaningful approach towards solving the complexities in current reimbursement process and the uncertainty that follows approval of a new product.

The National Venture Capital Association (NVCA), the venture industry's trade association advocating on behalf of the startup community, in collaboration with the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association (MDMA), conducted a survey of medical device investors to capture information on hurdles to investing in innovative medical technology products.

The survey was conducted over the web using Qualtrics between April 2 and April 9 of 2021. 65 useable responses were collected. The complete questionnaire along with results shown in aggregate form are presented below.

Questionnaire

Q1: Please indicate the total number of medical device, digital health, or diagnostics companies that your firm has invested in since January 1, 2018 (both new commitments or follow-ons).

Average number of companies per firm: 55.6
Median number of companies per firm: 27.5

Q2: Please indicate the total number of medical device, digital health, or diagnostics companies WITH a Breakthrough Designated product that your firm has invested in since January 1, 2018 (both new commitments or follow-ons).

# of Companies	# Responses	% of Total
0	14	21.9%
1	18	28.1%
2	8	12.5%
3	13	20.3%
4	6	9.4%
5	3	4.7%
6	2	3.1%

Average number of companies per firm: 3.5
Median number of companies per firm: 3.0

Q3: With respect to investing in innovative medical technology companies, please rank order the following hurdles along the path to value creation according to how challenging or intimidating you perceive these in a way that might reduce your willingness to invest: (1 = most intimidating, 5 = least intimidating)

1. Completing product development (before clinical studies)
2. Generating compelling clinical evidence
3. Obtaining FDA approval/clearance
4. Establishing new reimbursement paradigm (e.g., getting payor coverage policies)
5. Executing commercially

Hurdle	**Rank**				
	1	**2**	**3**	**4**	**5**
Completing product development (before clinical studies)	10	4	9	13	25
Generating compelling clinical evidence	3	18	21	11	2
Obtaining FDA approval/clearance	6	17	20	16	2
Establishing new reimbursement paradigm (e.g., getting payor coverage policies)	41	7	0	1	13
Executing commercially	2	16	14	20	12

Q4: With respect to a novel medical technology innovation that has received FDA approval and needs to then establish a reimbursement paradigm, please estimate the typical additional time and investment capital POST-FDA approval required for a start-up company to achieve an exit.

Est. Amount of Additional Time Required (in Years)	# Responses	% of Total
0	0	0.0%
1	0	0.0%
2	4	6.2%
3	16	24.6%
4	15	23.1%
5	19	29.2%
6	7	10.8%
7	2	3.1%
8	2	3.1%

Average estimated amount of additional time required: 4.3 years
Median estimated amount of additional time required: 4.5 years

Average estimated amount of additional investment capital required: $60.9 million
Median estimated amount of additional investment capital required: $50.0 million

Q5: If an early stage (seed or product development) company developing a novel medical technology will need to establish a new reimbursement paradigm (e.g., getting new payor coverage policies) for its product/procedure after generating clinical evidence and obtaining FDA approval, which of the following statements best describes your willingness to invest in that company today?

1. Not willing – in general, we avoid investing in companies that need to develop a new reimbursement paradigm
2. Less willing – in general, we will only invest in companies that need to establish a new reimbursement paradigm in exceptional circumstances
3. No impact – in general, whether a company can use an existing reimbursement paradigm or needs to establish a new reimbursement paradigm does not factor into our investment decisions
4. More willing – in general, we somewhat prioritize investing in companies that need to establish a new reimbursement paradigm
5. Most willing – in general, we highly prioritize investing in companies that need to establish a new reimbursement paradigm

Statement	# Responses	% of Total
Not willing – in general, we avoid investing in companies that need to develop a new reimbursement paradigm	11	17.2%
Less willing – in general, we will only invest in companies that need to establish a new reimbursement paradigm in exceptional circumstances	48	75.0%
No impact – in general, whether a company can use an existing reimbursement paradigm or needs to establish a new reimbursement paradigm does not factor into our investment decisions	4	6.3%
More willing – in general, we somewhat prioritize investing in companies that need to establish a new reimbursement paradigm	0	0.0%
Most willing – in general, we highly prioritize investing in companies that need to establish a new reimbursement paradigm	1	1.6%

Q6: If a start-up company's medical technology innovation will ultimately require a new reimbursement framework (coding, coverage, payment) to be established in order to enable commercialization, what typically is the earliest stage at which you would be willing to make an initial investment in that start-up company?

1. Idea stage / company formation
2. Post product development completion
3. Post clinical evidence completion
4. Post FDA approval/clearance
5. Post reimbursement (coding, coverage, payment) established
6. Commercially scaling

Stage	# Responses	% of Total
Idea stage / company formation	5	7.8%
Post product development completion	10	15.6%
Post clinical evidence completion	27	42.2%
Post FDA approval/clearance	13	20.3%
Post reimbursement (coding, coverage, payment) established	9	14.1%
Commercially scaling	0	0.0%

Q7: Please indicate your level of agreement with the following statement: "If the proposed MCIT rule for Breakthrough Designated Devices is implemented and those products could receive four years of immediate Medicare coverage upon FDA approval, on average, I would be willing to invest at earlier stages of medical technology product development than I do today."

1. Strongly Agree
2. Agree
3. Neutral
4. Disagree
5. Strongly Disagree

Level of Agreement	# Responses	% of Total
Strongly agree	56	87.5%
Agree	5	7.8%
Neutral	2	3.1%
Disagree	0	0.0%
Strongly disagree	1	1.6%

Q8: With respect to FDA Breakthrough Device designation pathway, and if MCIT is implemented, what do you perceive is the most important potential benefit of receiving Breakthrough Designation?

1. Prestige/branding/validation
2. More efficient FDA review process/timeline
3. More collaboration/engagement with FDA on the standard or expectations for obtaining review and approval
4. Possibility of earlier (upon post-FDA approval) patient access via coverage for Medicare beneficiaries for four years through the MCIT pathway

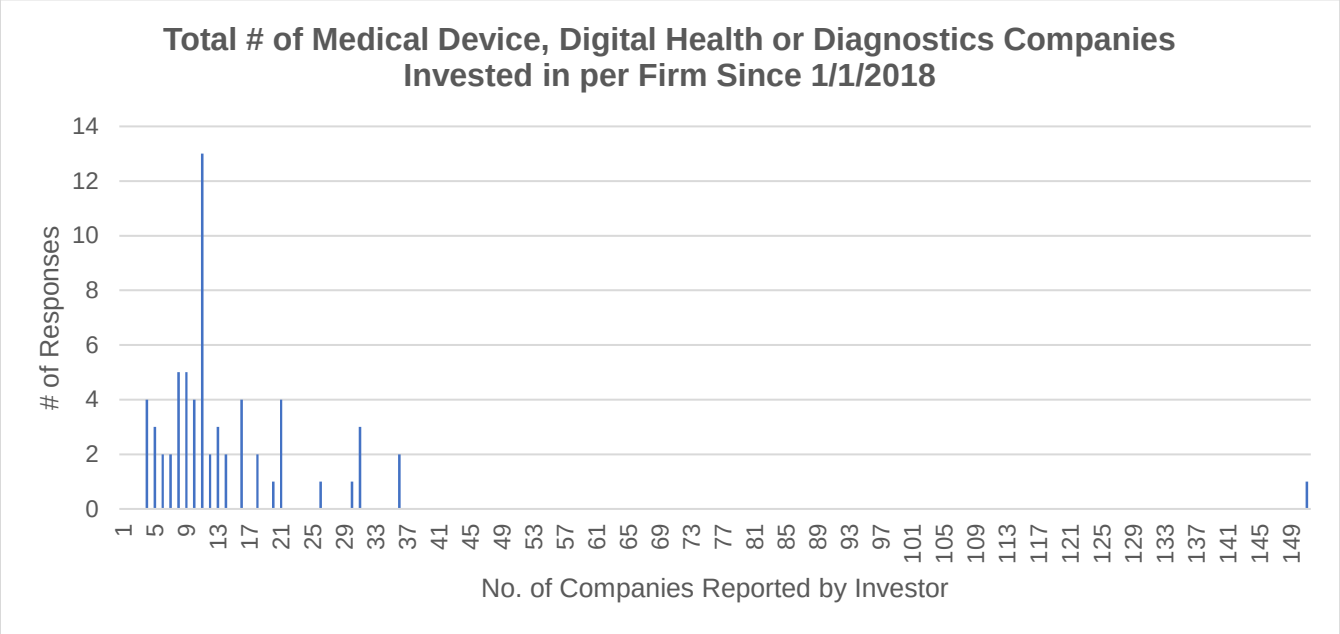
Perceived Most Important Potential Benefit	# Responses	% of Total
Prestige/branding/validation	0	0.0%
More efficient FDA review process/timeline	2	3.1%
More collaboration/engagement with FDA on the standard or expectations for obtaining review and approval	5	7.8%
Possibility of earlier (upon FDA approval) patient access via coverage for Medicare beneficiaries for four years through the MCIT pathway	57	89.1%

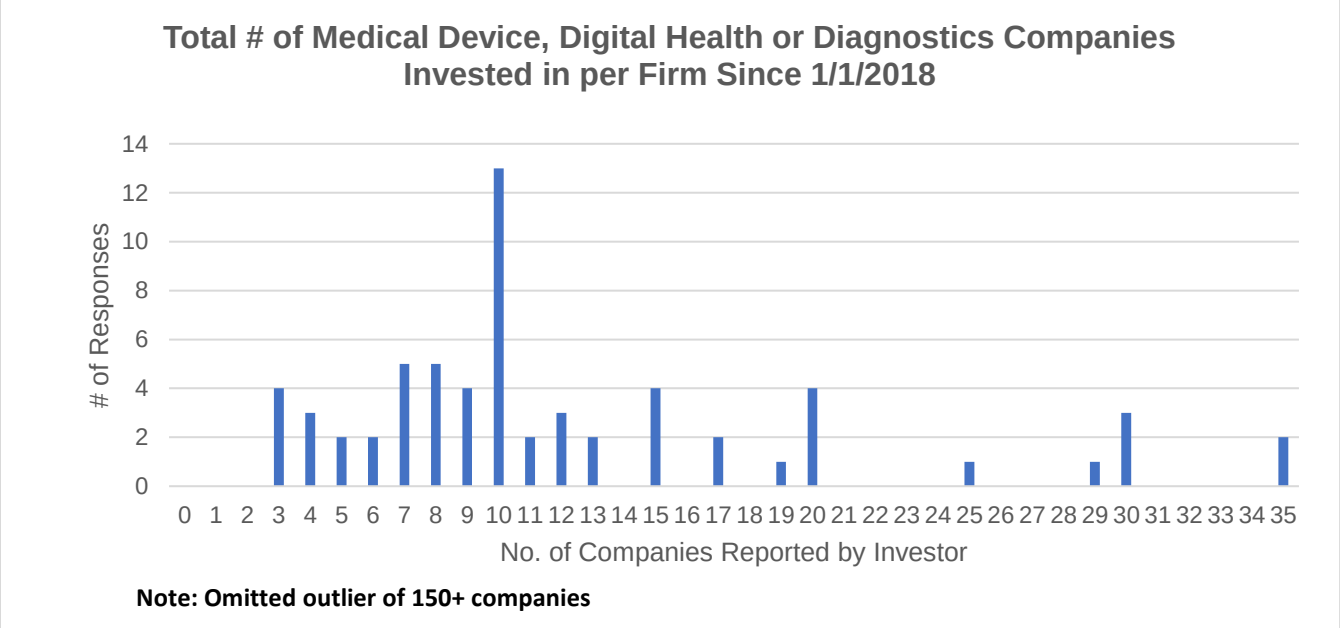
Methodology notes:

1. In cases where a numerical response was given as “X+”, the response was mapped to strictly “X”.
2. In cases where a numerical response was given as a range, such as “from X to Y”, the response was mapped to the midpoint (average) of “X” and “Y”.

Charts

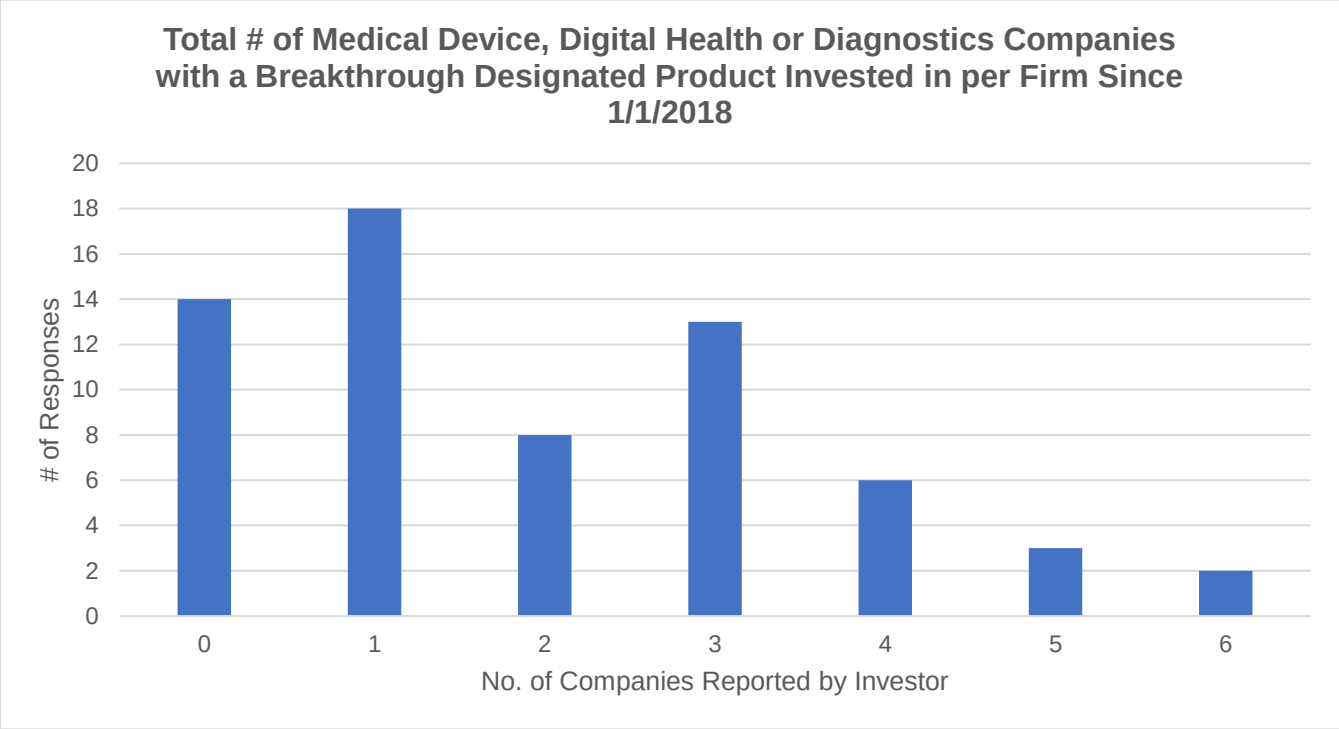
Question 1



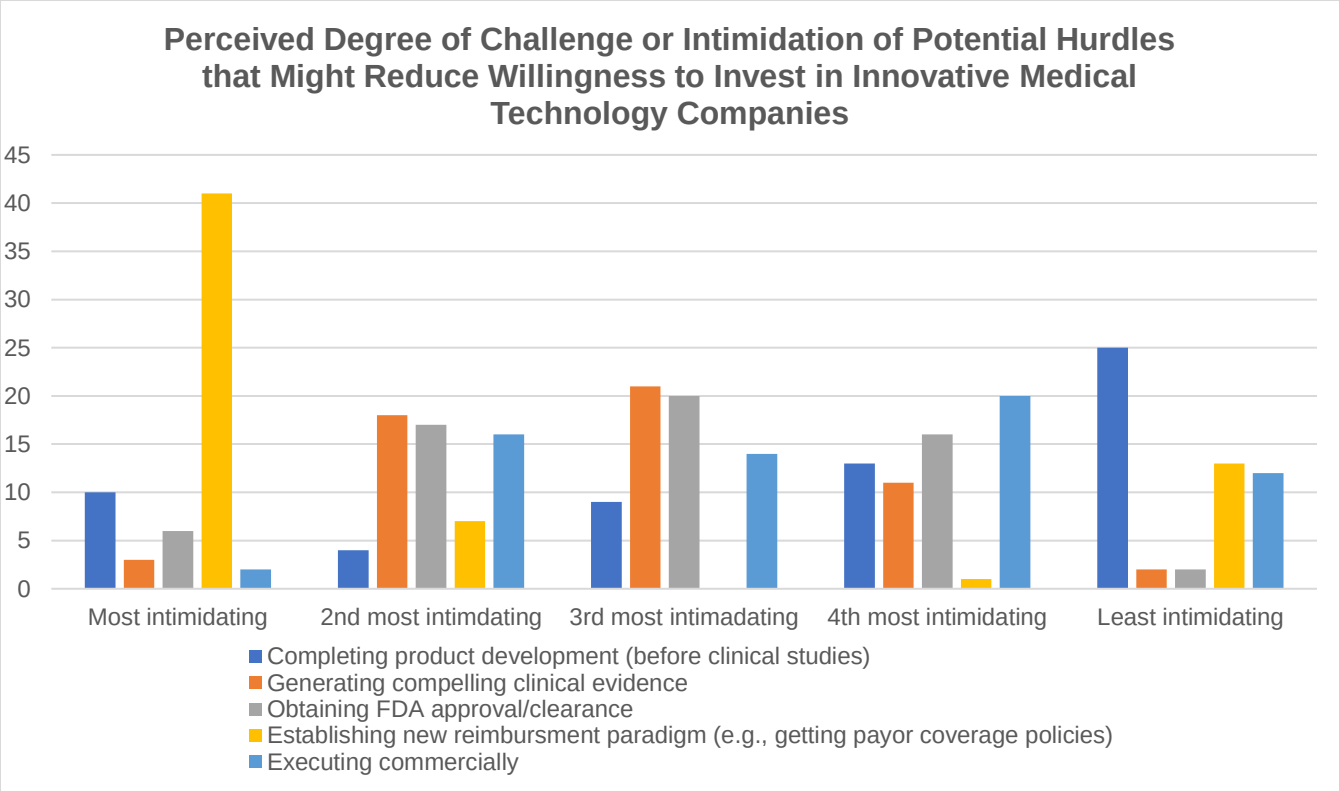


Note: Omitted outlier of 150+ companies

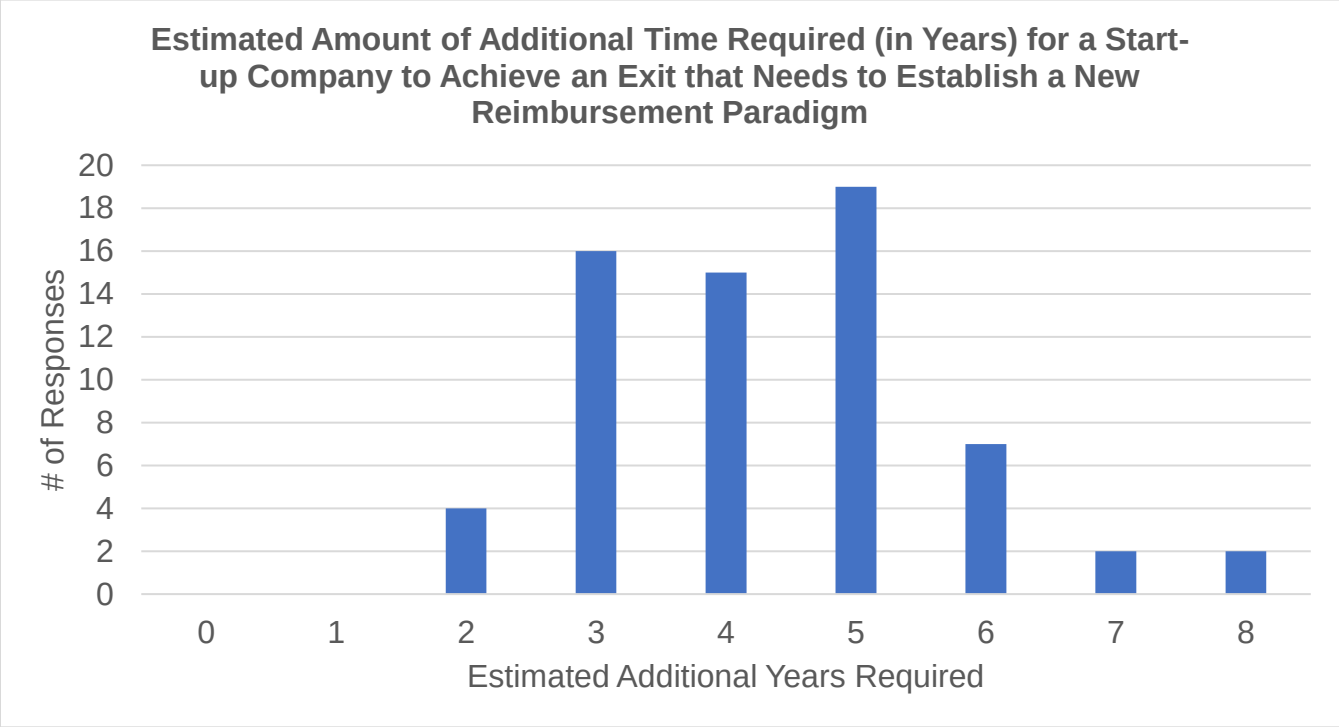
Question 2

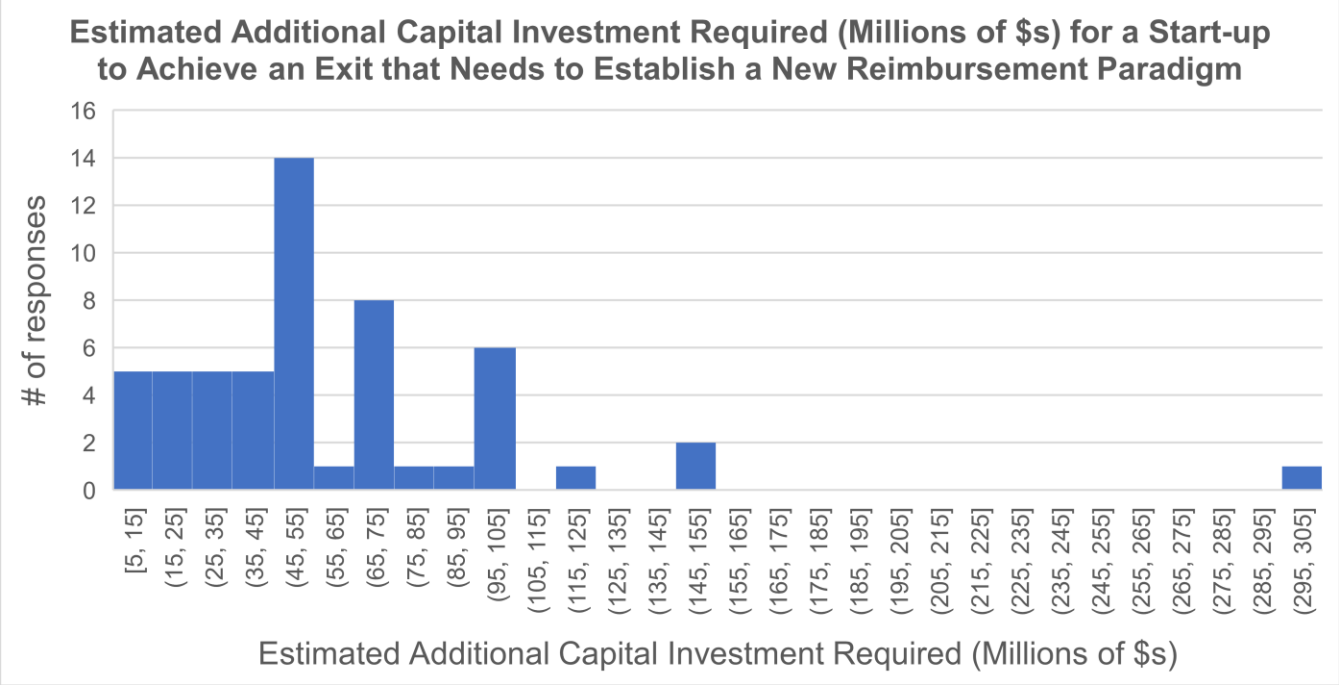


Question 3



Question 4


Estimated Amount of Additional Time Required (in Years) for a Start-up Company to Achieve an Exit that Needs to Establish a New Reimbursement Paradigm
# of Responses
20
18
16
14
12
10
8
6
4
2
0
0
1
2
3
4
5
6
7
8
Estimated Additional Years Required


Estimated Additional Capital Investment Required (Millions of $s) for a Start-up to Achieve an Exit that Needs to Establish a New Reimbursement Paradigm
# of responses
16
14
12
10
8
6
4
2
0
[5, 15]
(15, 25]
(25, 35]
(35, 45]
(45, 55]
(55, 65]
(65, 75]
(75, 85]
(85, 95]
(95, 105]
(105, 115]
(115, 125]
(125, 135]
(135, 145]
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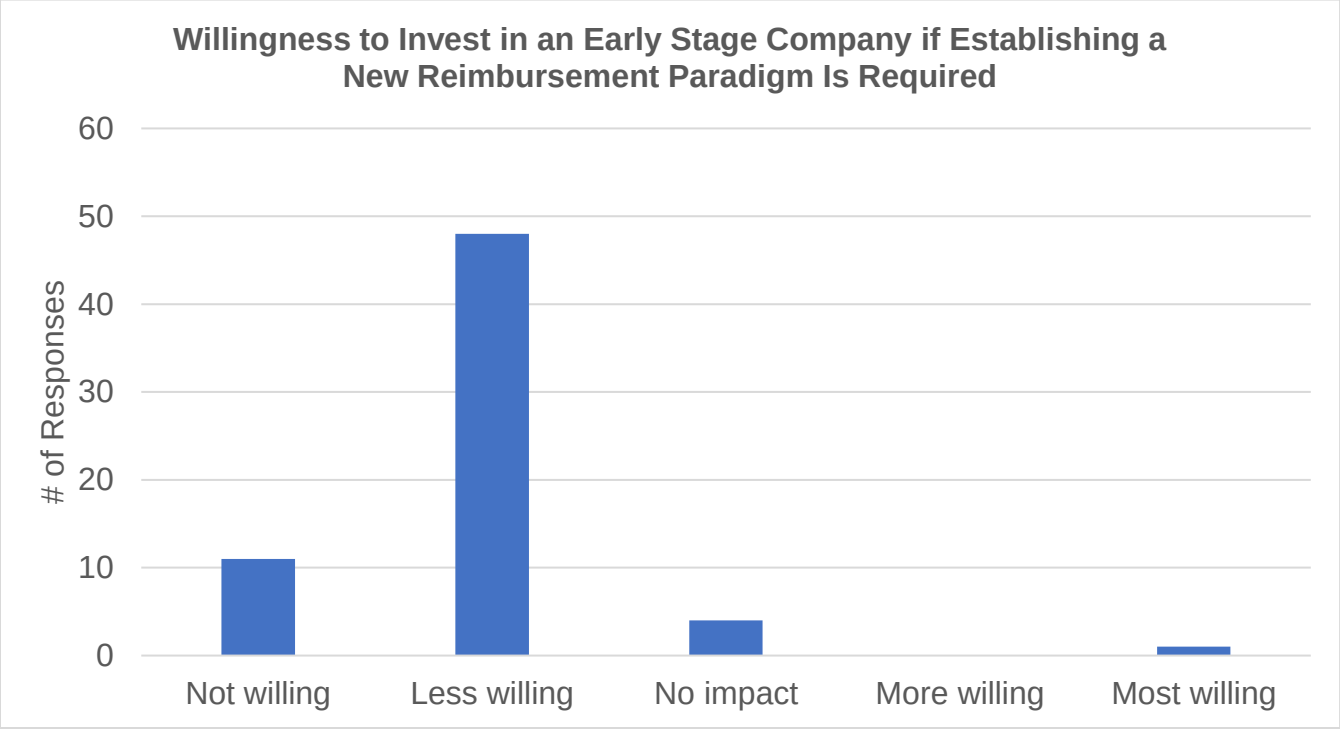
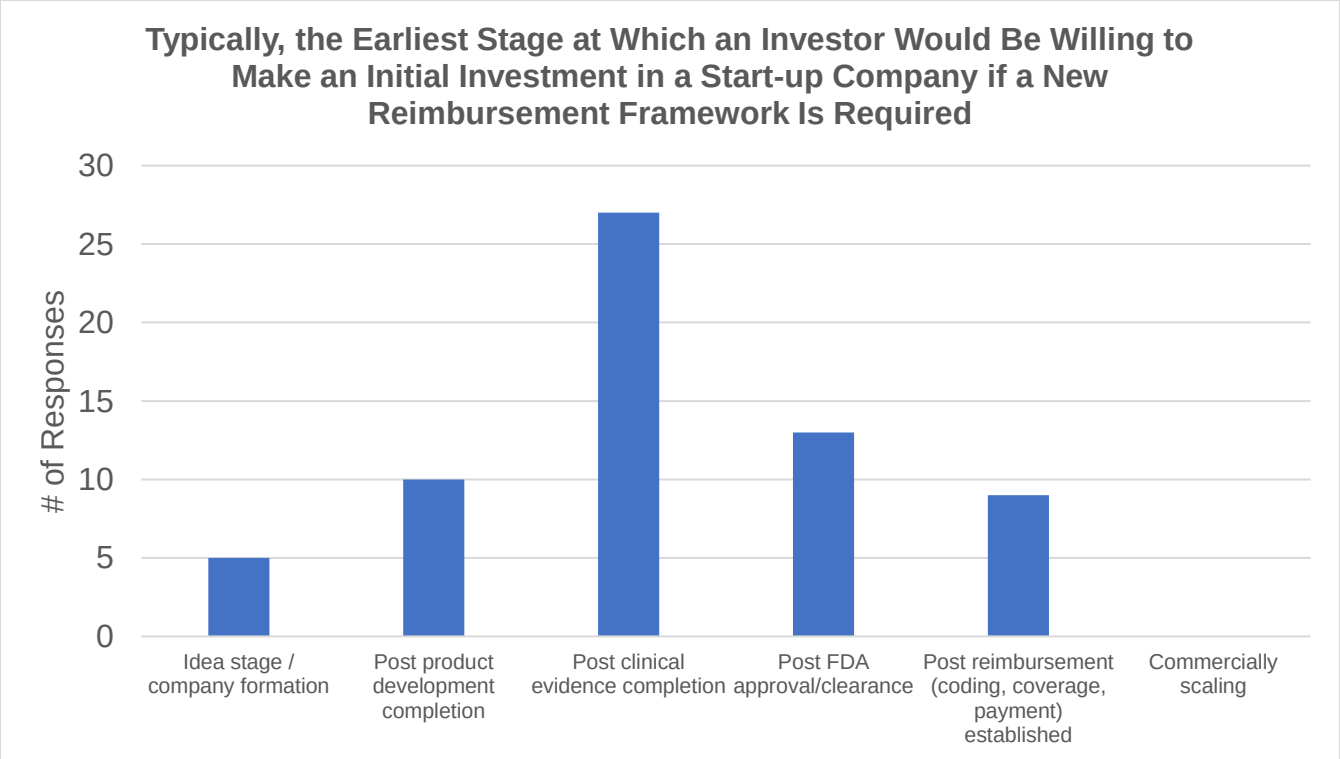
(275, 285]
(285, 295]
(295, 305]
Estimated Additional Capital Investment Required (Millions of $s)

Question 5

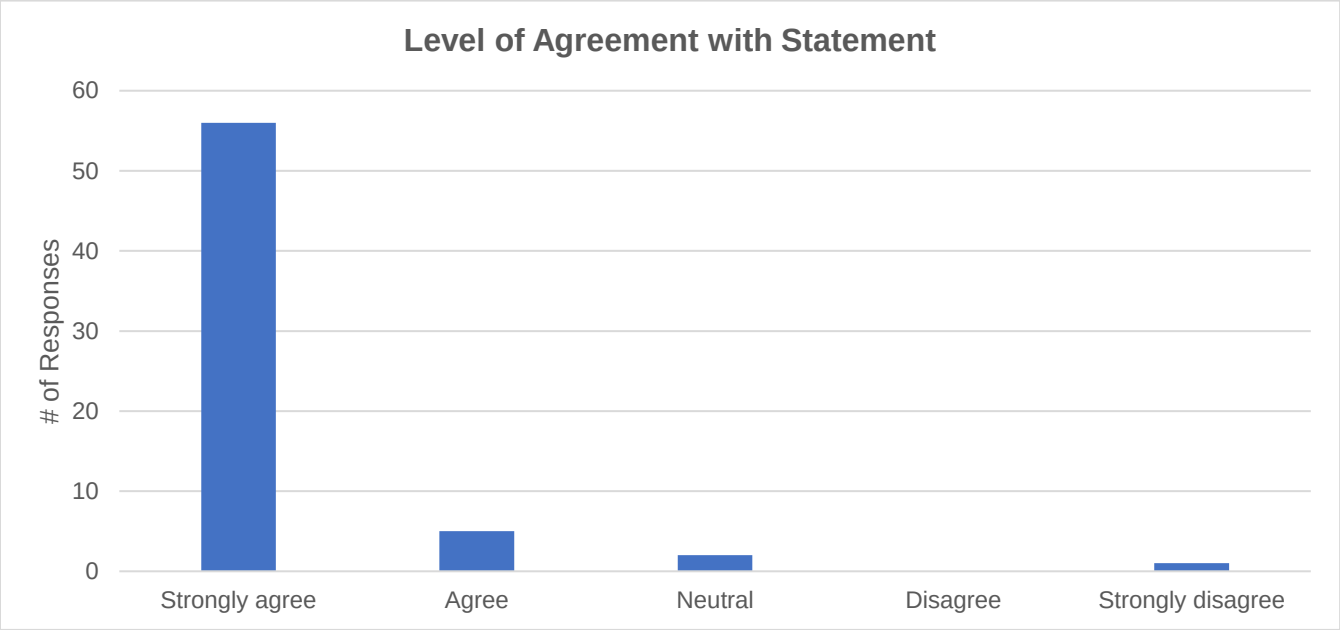


Question 6



Question 7

Statement: “If the proposed MCIT rule for Breakthrough Designated Devices is implemented and those products could receive four years of immediate Medicare coverage upon FDA approval, on average, I would be willing to invest at earlier stages of medical technology product development than I do today.”



Question 8