

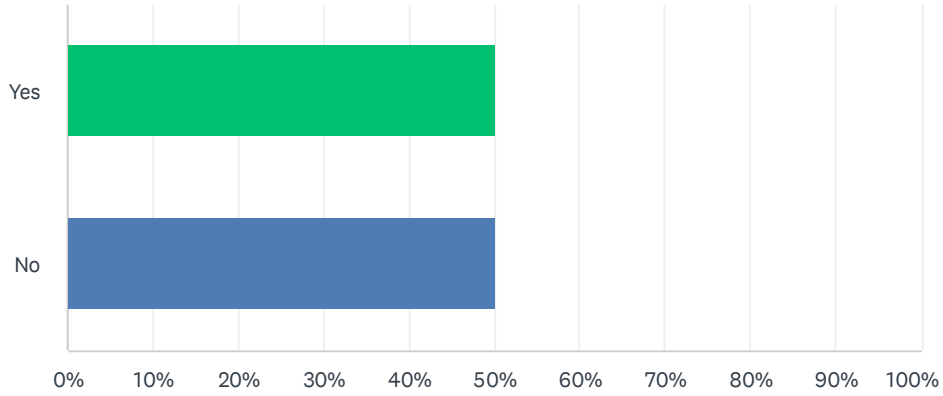
Q1 Please provide your individual Survey Monkey code provided to you by Julian Arbuckle:

Answered: 9 Skipped: 1

#	RESPONSES	DATE
1	2772	10/28/2022 7:26 PM
2	7507	10/26/2022 8:55 PM
3	??	10/26/2022 5:05 PM
4	4099	10/15/2022 3:17 PM
5	2276	10/14/2022 11:50 PM
6	2167	10/6/2022 11:42 PM
7	8354	10/6/2022 1:42 PM
8	4510	10/6/2022 10:17 AM
9	3287	10/5/2022 5:40 PM

Q2 Does your organization use digital biomarkers in its clinical programs development?

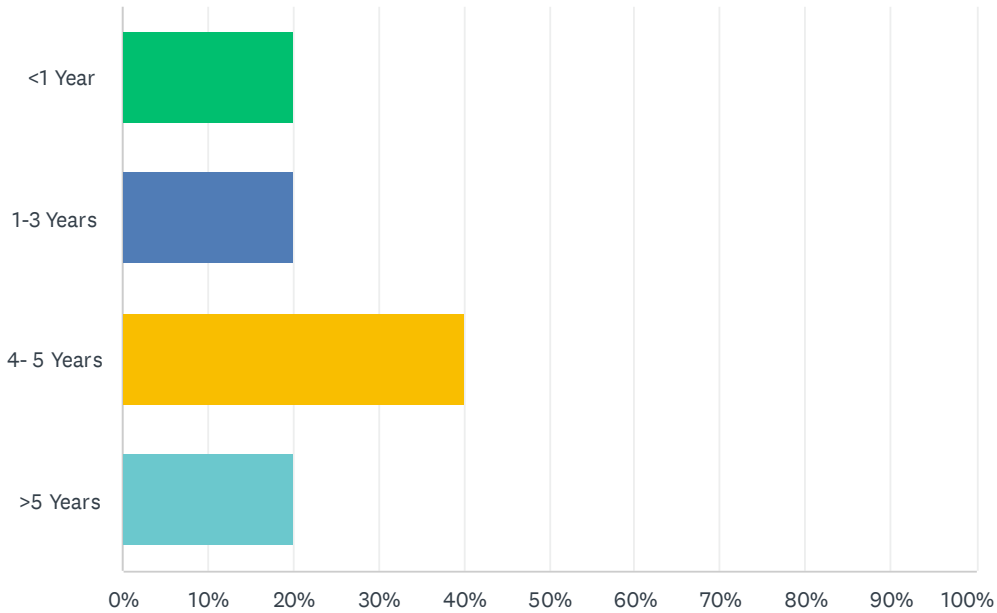
Answered: 10 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	50.00%	5
No	50.00%	5
TOTAL		10

Q3 If you answered "No" to Q2 you have completed the survey. If you answered "Yes" to Q2 for how long has this program been in place?

Answered: 5 Skipped: 5



ANSWER CHOICES	RESPONSES
<1 Year	20.00% 1
1-3 Years	20.00% 1
4- 5 Years	40.00% 2
>5 Years	20.00% 1
TOTAL	5

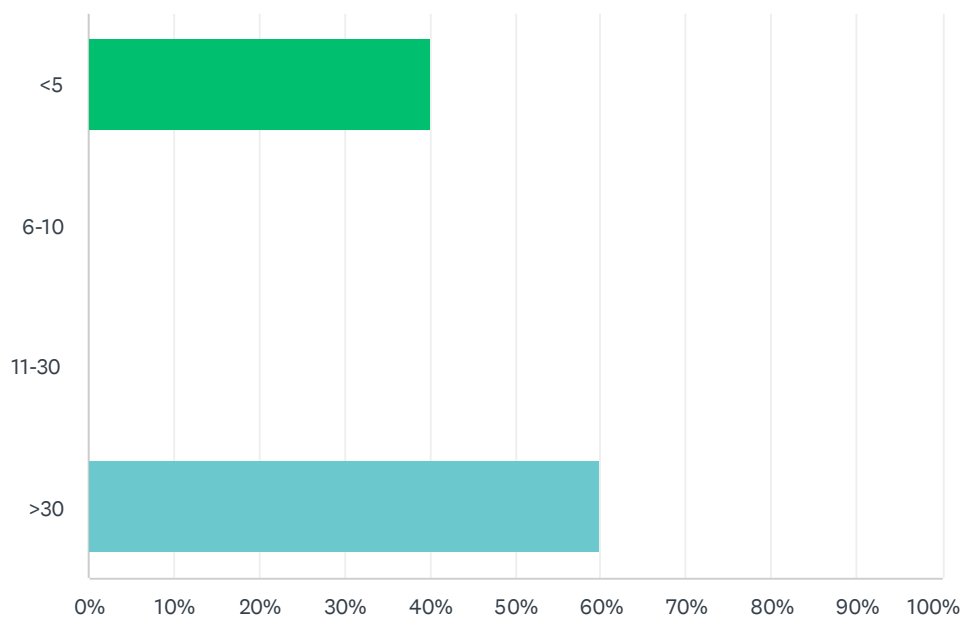
Q4 In what therapeutic areas does your organization focus on for digital biomarkers?

Answered: 5 Skipped: 5

#	RESPONSES	DATE
1	Immunology & Inflammation; Vaccines/Anti-virals; Rare diseases; Internal medicine	10/28/2022 7:26 PM
2	Several	10/28/2022 10:01 AM
3	CV, IM, some Onc	10/26/2022 5:05 PM
4	rare disease space	10/6/2022 11:42 PM
5	Neurosciences	10/6/2022 10:17 AM

Q5 How many persons work in biomarker research in your organization?

Answered: 5 Skipped: 5



ANSWER CHOICES	RESPONSES
<5	40.00% 2
6-10	0.00% 0
11-30	0.00% 0
>30	60.00% 3
TOTAL	5

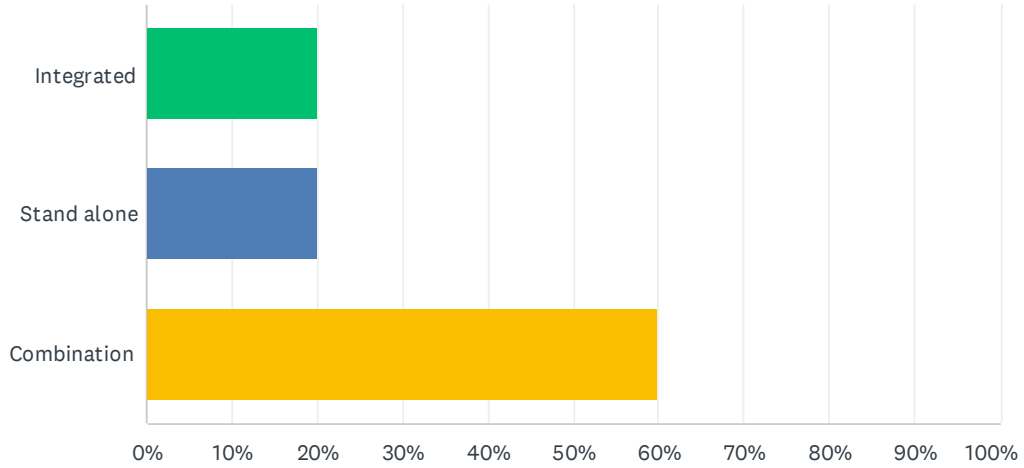
Q6 How many asset programs is each individual responsible for?

Answered: 4 Skipped: 6

#	RESPONSES	DATE
1	~4	10/28/2022 7:26 PM
2	3-5	10/26/2022 5:05 PM
3	3-4	10/6/2022 11:42 PM
4	2-3	10/6/2022 10:17 AM

Q7 Are digital biomarkers integrated into global biomarkers (i.e. tissue/fluid/imaging based) plans or standalone programs outside of canonical biomarkers?

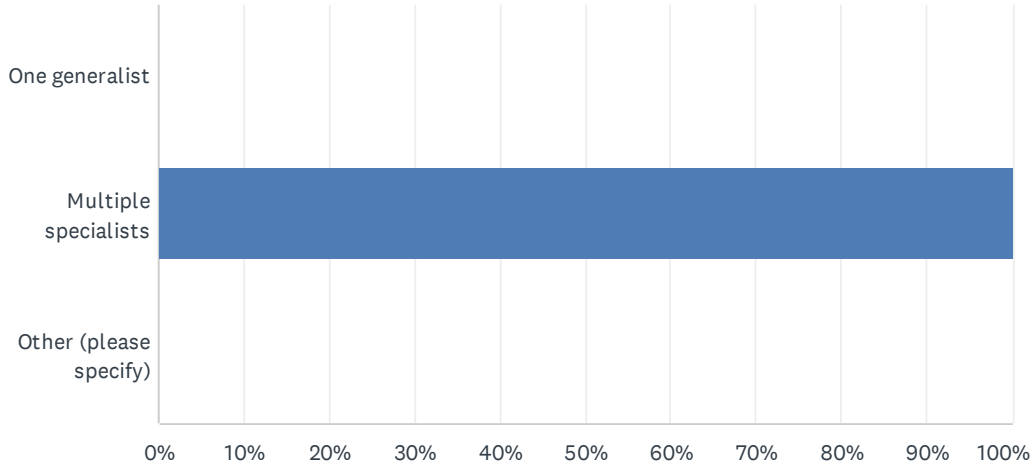
Answered: 5 Skipped: 5



ANSWER CHOICES	RESPONSES
Integrated	20.00% 1
Stand alone	20.00% 1
Combination	60.00% 3
TOTAL	5

Q8 If you answered "Integrated" to Q7 does one team member handle both the global and digital biomarkers plans or is there a specialized member for each global and digital biomarkers?

Answered: 1 Skipped: 9

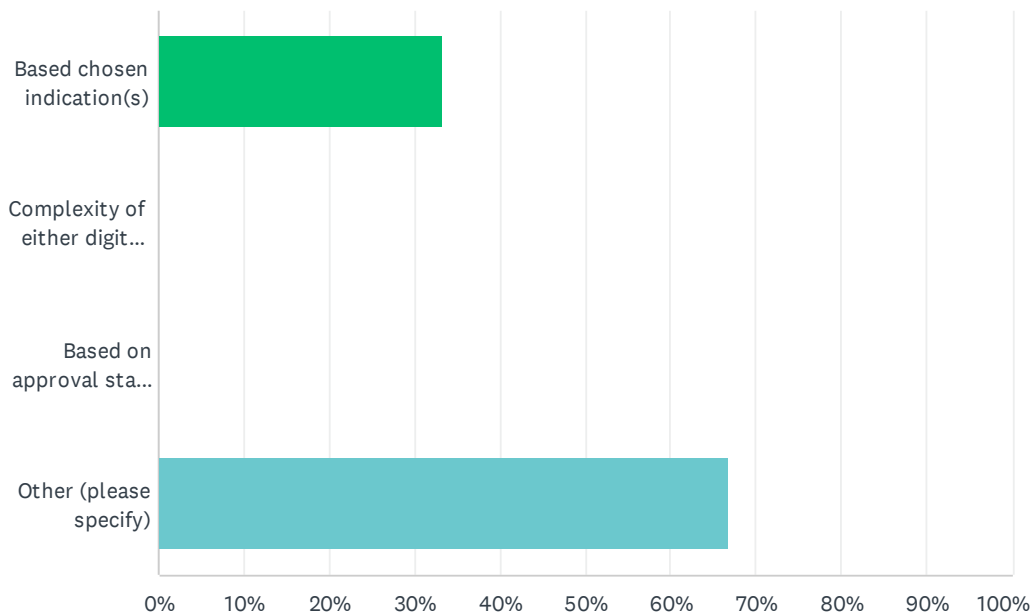


ANSWER CHOICES	RESPONSES
One generalist	0.00% 0
Multiple specialists	100.00% 1
Other (please specify)	0.00% 0
TOTAL	1

#	OTHER (PLEASE SPECIFY)	DATE
	There are no responses.	

Q9 If you answered "Combination" to Q7 how does your organization decide whether to integrate or split off digital biomarker project?

Answered: 3 Skipped: 7



ANSWER CHOICES	RESPONSES
Based chosen indication(s)	33.33% 1
Complexity of either digital or canonical biomarker programs	0.00% 0
Based on approval status (i.e. Pre vs. Post FDA approval)	0.00% 0
Other (please specify)	66.67% 2
TOTAL	3

#	OTHER (PLEASE SPECIFY)	DATE
1	Based on the current scientific evidence and the intended concept of interest and stage of development it will impact.	10/28/2022 7:26 PM
2	based on study scope	10/28/2022 10:01 AM

Q10 If digital biomarkers are separate from other biomarkers, how are they integrated into the larger clinical development plan (including attending meetings, creating awareness etc.)?

Answered: 2 Skipped: 8

#	RESPONSES	DATE
1	These are either independent clinical development plans or integrated into the investigational drug product's clinical development plan.	10/28/2022 7:26 PM
2	We do not have a specific digital biomarker group; digital biomarkers (eDiaries or speech analytic devices for example) will be included in clinical protocols based on where the field is at, or based on clinician working groups developing them. Input for advocacy groups, who may be supporting such assessments, also factors into how these biomarkers get included in a program. These tools often revolve around better understanding quality-of-life outside of specific clinician-assessed tests. Discussion of the results of these biomarkers will occur at regular team meetings with the larger group.	10/6/2022 11:42 PM

Q11 In your experience, what are some key features that facilitate the development and implementation of digital biomarkers into clinical programs?

Answered: 4 Skipped: 6

#	RESPONSES	DATE
1	Subject matter expertise; independent data science and algorithm and medical teams to support validation and qualification packages; additional digital health technology regulatory experience.	10/28/2022 7:26 PM
2	vendor operation readiness	10/28/2022 10:01 AM
3	Robustness of the digital biomarker - has it been used in other studies, is the analytical aspect well-known and is there a correlation to disease progression. Will it be easy to use and easy to deploy in multiple sites across multiple jurisdictions or with different patient populations.	10/6/2022 11:42 PM
4	support from other functions (med. affairs, commercial) to show potential value generated	10/6/2022 10:17 AM

Q12 In your experience, what are some key features that inhibit the development and implementation of digital biomarkers into clinical programs?

Answered: 4 Skipped: 6

#	RESPONSES	DATE
1	Lack of focus on development of subject matter expertise and scaling of best practices across organization. in addition, the senior management must support and boot-strap groups concept development and demonstration of value.	10/28/2022 7:26 PM
2	assessment complexity, technology maturity level, vendors compliance levels	10/28/2022 10:01 AM
3	Lack of transparency how the device captures the measurement in question; lack of flexibility for data analysis (i.e. some companies may not provide the algorithm behind how activity is measured - this may be an issue to truly understand what is measured); lack of specificity for a particular disease	10/6/2022 11:42 PM
4	adding complexity to the trial	10/6/2022 10:17 AM

Q13 If there is any other feedback that you would like to provide as part of this survey then please let us know:

Answered: 1 Skipped: 9

#	RESPONSES	DATE
1	In a perfect world, companies would work together in a pre-competitive manner to test out a few activity meters, for example, in different muscular disease and the data would be shared, and the field could decide together on what device is best for disease X versus disease Y. the goal would be to more quickly and transparently develop the best digital biomarker that can be used by multiple companies for faster drug approvals. This would result in patients getting better treatments faster.	10/6/2022 11:42 PM