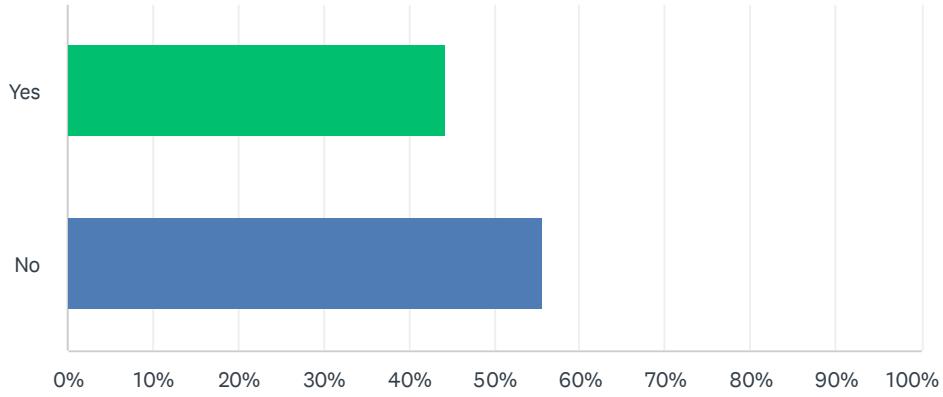
# Q1 Please enter your unique Survey Monkey code provided to you by Julian Arbuckle:

Answered: 8 Skipped: 1

| # | RESPONSES | DATE |
|---|---|---|
| 1 | 7333 | 8/25/2022 9:07 PM |
| 2 | 2999 | 8/25/2022 4:42 PM |
| 3 | 3444 | 8/22/2022 2:24 PM |
| 4 | 4099 | 8/19/2022 12:40 PM |
| 5 | 7709 | 8/15/2022 5:16 PM |
| 6 | 1902 | 8/3/2022 4:37 AM |
| 7 | 2299 | 7/20/2022 10:36 PM |
| 8 | 2276 | 7/15/2022 12:07 AM |

# Q2 Does your company retain biospecimens from clinical trial sites in Belgium for use outside of (or after) the trial? Yes/No (If your response is No, the rest of the questions are not applicable.)

Answered: 9 Skipped: 0




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 44.44% | 4 |
| No | 55.56% | 5 |
| Total Respondents: 9 | | |

# Q3 What are these biospecimens used for?

Answered: 4 Skipped: 5

| # | RESPONSES | DATE |
|---|---|---|
| 1 | Future research to investigate/understand adverse drug reactions | 8/25/2022 9:07 PM |
| 2 | See question 4. | 8/25/2022 4:42 PM |
| 3 | Exploratory research and test/tool development related to the disease and drug under investigation in the clinical study | 8/22/2022 2:24 PM |
| 4 | These biospecimens are for research that may be in the future and may be outside of the study endpoints. As described in the ICD and protocol, it is limited to research related to the study drug and study disease. These biospecimens may include residual material from samples collected for study testing as well as samples collected expressly for these ex-study testing purposes. | 8/3/2022 4:37 AM |

# Q4 Are any of your biospecimen-related activities in scope of the Belgian Biobank Decree of 2018? Please describe. (If your response is No, the rest of the questions are not applicable.)

Answered: 4 Skipped: 5

| # | RESPONSES | DATE |
|---|---|---|
| 1 | Yes, but this is under evaluation. We are just working with the first samples collected at a Belgian CRO | 8/25/2022 9:07 PM |
| 2 | NO – retained biospecimens are pre- Belgian Biobank Decree of 2018 and moving forward, processes are being put in place to ensure that samples from Belgium participants are only used for primary study use and within relevant approval. | 8/25/2022 4:42 PM |
| 3 | No, there is an agreement that as long as we restrict the scope of use of the samples to research on the disease and IMP under investigation in the clinical study, biospecimen- related activities are not in scope of the Belgian Biobank Decree of 2018. | 8/22/2022 2:24 PM |
| 4 | The wording of the Decree can be interpreted as these samples being either in-scope or out-of-scope, and official guidance from Belgian authorities has not been released to clarify. | 8/3/2022 4:37 AM |

# Q5 What approaches or steps, if any, has your company taken to comply with the Belgian Biobank Decree? Please describe your experience:

Answered: 2 Skipped: 7

| # | RESPONSES | DATE |
|---|---|---|
| 1 | The Belgian site used is considered a Biobank and we plan to register all samples from the applicable study in this Biobank to comply with the regulations | 8/25/2022 9:07 PM |
| 2 | . We have consulted local legal and regulatory counsel, however have not arrived at a final position as to what direction or actions to take. Since 2018 we have been collecting these biospecimens with the understanding they are out-of-scope because they are collected during clinical trials and their uses are stated in the study document(s). Since 2018 we have been receiving approvals from local authorities who reviewed the study materials (ECs, FAMPF). | 8/3/2022 4:37 AM |

# Q6 Has your company performed a biobank notification in Belgium? Please describe your experience.

Answered: 2 Skipped: 7

| # | RESPONSES | DATE |
|---|---|---|
| 1 | Yes, but I have been unable to obtain details on the interaction from those involved. | 8/25/2022 9:07 PM |
| 2 | No. | 8/3/2022 4:37 AM |