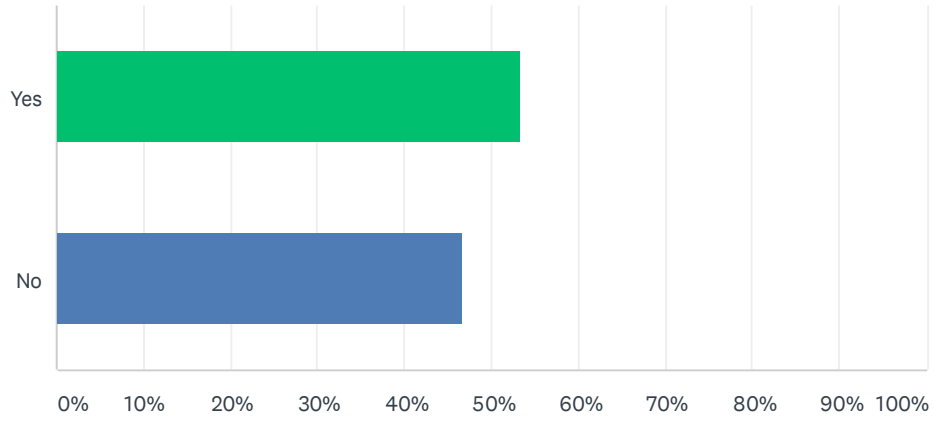
Q1 Please enter the unique individual Survey Monkey code provided to you by Julian Arbuckle:

Answered: 14 Skipped: 1

#	RESPONSES	DATE
1	3287	4/3/2021 3:16 AM
2	0921	3/31/2021 8:22 AM
3	2772	3/30/2021 8:20 PM
4	8354	3/30/2021 6:38 PM
5	4099	3/30/2021 4:58 AM
6	2276	3/29/2021 10:34 PM
7	8008	3/29/2021 6:07 PM
8	5965	3/29/2021 3:47 PM
9	7333	3/29/2021 1:58 PM
10	3444	3/25/2021 4:17 PM
11	2531	3/25/2021 1:15 AM
12	1011	3/24/2021 11:25 PM
13	4001	3/22/2021 3:55 PM
14	1003	3/19/2021 12:20 AM

Q2 Is your biorepository inventory management system deemed as a GxP IT system?

Answered: 15 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	53.33%	8
No	46.67%	7
TOTAL		15

Q3 What where the reasons that contributed to the GxP or non-GxP designation?

Answered: 15 Skipped: 0

#	RESPONSES	DATE
1	Compliance with downstream data feeds	4/3/2021 3:16 AM
2	To be compliant with Belgian regulations	3/31/2021 8:22 AM
3	We did not choose whether it would be GxP or non-GxP. The vendor we use happens to have a GxP system so that's what is used for our company. The vendor is GxP because they manage samples for primary and secondary endpoints in clinical trials.	3/30/2021 8:20 PM
4	The system contains sample information for GCP and GLP studies, as well as result data from GCP studies. Sample and result data may also be transferred from the sample management system to the clinical trial database for GCP studies. System is CFR Part 11 compliant and maintains an audit trail of each sample.	3/30/2021 6:38 PM
5	Our inventory management system was designed to support GxP decision making, such as authorized use of residual or exploratory samples, without the user having to cross-reference with a validated GxP system. Therefore, we consider this system GxP.	3/30/2021 4:58 AM
6	External biorepository	3/29/2021 10:34 PM
7	genomic studies are being performed as exploratory. We continue to evaluate this internally.	3/29/2021 6:07 PM
8	We did not initiate GxP/non-GxP-compliant designated biorepositories	3/29/2021 3:47 PM
9	We don't have a single biorepository yet and so not all inventory systems are GxP. We are piloting an external biorepository solution in the 2021/2022 timeframe and GxP compliance is part of the evaluation.	3/29/2021 1:58 PM
10	Management of clinical trial samples	3/25/2021 4:17 PM
11	we do not have such system yet	3/25/2021 1:15 AM
12	Internal regulatory compliance group's interpretation of GCP guidelines	3/24/2021 11:25 PM
13	unknown	3/24/2021 10:23 PM
14	Our LIMS system supports both CLIA and other Clinical (GCP/GCLP) studies.	3/22/2021 3:55 PM
15	1- The system amalgamates inventory information from multiple vendors, and is not the system of record for any of the data it contains (i.e. the system is a shadow system of data created and maintained in vendor GxP systems). 2- The system is a stand-alone system that is not interfaced with any other GxP system. 3- System is a SaaS solution, performance of which has been validated by the vendor. 3- We are not currently intending to submit data contained within the system for any regulatory findings. Any chain of custody documentation will be furnished by our vendors.	3/19/2021 12:20 AM

Q4 If GxP-designated, how many FTE is allocated to maintaining the system to GxP standards?

Answered: 15 Skipped: 0

#	RESPONSES	DATE
1	2	4/3/2021 3:16 AM
2	One	3/31/2021 8:22 AM
3	Not known-- this information is internal to our biorepository vendor. Our company has a department that "audits" vendors' systems-- but this may be different from what the question is asking about. Not sure how much FTE to allocate to auditing our biorepository IT system.	3/30/2021 8:20 PM
4	3 FTE - system has been in place for several year so less FTE are needed now for continued maintenance	3/30/2021 6:38 PM
5	Three.	3/30/2021 4:58 AM
6	Not applicable	3/29/2021 10:34 PM
7	NA	3/29/2021 6:07 PM
8	NA	3/29/2021 3:47 PM
9	n/a	3/29/2021 1:58 PM
10	Difficult to answer this question, the system needs to evolve so we have a dedicated IT team for change requests management & implementation as well as keeping all of the documentation in order. This is at least 3 FTE.	3/25/2021 4:17 PM
11	None	3/25/2021 1:15 AM
12	10 on a day-to-day basis, more if validation work is needed on a project basis	3/24/2021 11:25 PM
13	n/a	3/24/2021 10:23 PM
14	2 - 3 FTE (IT and Administration) Other FTE (Lab Staff for testing/use)	3/22/2021 3:55 PM
15	n/a	3/19/2021 12:20 AM

Q5 Is there any other feedback or comments that you would like to provide to us in relation to LIMS and GxP processes?

Answered: 10 Skipped: 5

#	RESPONSES	DATE
1	The system is GxP compliant, but not certified	3/31/2021 8:22 AM
2	We prefer processes/IT systems to be GxP because it provides flexibility to manage a variety of samples, some of which may require GxP.	3/30/2021 8:20 PM
3	LIMS system in place is highly customized to our process, and system has undergone significant enhancements to meet our specific needs.	3/30/2021 6:38 PM
4	Agency guidance is often ambiguous when it comes to systems that support the management of specimen inventory but do not capture clinical data. Our team continues to evaluate what aspects of our systems should influence the validated state of the system.	3/30/2021 4:58 AM
5	No	3/29/2021 10:34 PM
6	In our perspective it is better to have GxP-compliant LIMS and biorepositories, which provide additional quality/accuracy	3/29/2021 3:47 PM
7	No	3/29/2021 1:58 PM
8	Some of FTE is based on the number of studies in the system (Biobanking staff), rest is system support and testing documentation that is independent of number of studies in the system (Systems staff).	3/24/2021 11:25 PM
9	no	3/24/2021 10:23 PM
10	It's a bit hard to answer without further context: you trying to build new GxP, considering whether you need to be GxP, do you already a LIMS? Are you sending samples to GxP lab? Would be happy to provide further thoughts based on context. :) Depending on the LIMS you are using or choosing, internal expertise is critical to continued functionality and oversight.	3/22/2021 3:55 PM