#1

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Saturday, July 10, 2021 4:38:50 PM
Last Modified:	Saturday, July 10, 2021 4:43:19 PM
Time Spent:	00:04:29
Email:	Guangqing.Xiao@sunovion.com
IP Address:	64.30.93.113

Page 1

Q1

What type of BIMS do you have?

Internally built (custom solution)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

Respondent skipped this question

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

,

To record sample-related data such as patient demographics or informed consent parameters

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

To support clinical decision making,

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

Respondent skipped this question

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

No

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

Respondent skipped this question

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We conduct our own internal validation procedure.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Respondent skipped this question

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

Respondent skipped this question

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

Respondent skipped this question

Q13

If you are able to overcome any of these challenges, please elaborate how:

Respondent skipped this question

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on determining how to assess validation needs

,

Guidance on how to meet regulatory requirements associated with BIMS

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members,

Other industry body,

Regulatory authority

Q16

What other items would you want to be addressed by a BIMS task force?

Respondent skipped this question

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

Respondent skipped this question

#2

COMPLETE

Collector:	Web Link 2 (Web Link)
Started:	Monday, July 12, 2021 10:35:16 AM
Last Modified:	Monday, July 12, 2021 10:56:09 AM
Time Spent:	00:20:52
IP Address:	160.62.3.1

Page 1

Q1

What type of BIMS do you have?

Commercial off-the-shelf, self-hosted

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

LabVantage

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

The validation was considered when we launched the first platform in 2006 and we decided to maintain it. The validation by itself doesn't affect the use cases.

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

No

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

Respondent skipped this question

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

No

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Clinical operations is supported by different organizations. The main challenge is to develop a solution that covers needs of all of them. Example, the sample reconciliation is managed differently depending on the groups.

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

Partially. We are in a process to revisit our platforms. I mentioned above that we use a commercial platform but 2 other in-house solutions are used to track samples for on-going trials. We launched an initiative to develop an unique platform for the tracking and reconciliation of on-going clinical trials.

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

One of the biggest challenges is the use of same standards between all parties (data management, clinical operations). Another challenge when multiple systems exist is the governance. With our next platform, the governance model will be essential.

Q13

If you are able to overcome any of these challenges, please elaborate how:

The governance model will be approved by the upper management to avoid any misunderstanding.

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on determining how to assess validation needs

,

Guidance on how to meet regulatory requirements associated with BIMS

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members,

Regulatory authority

Q16

What other items would you want to be addressed by a BIMS task force?

I would appreciate to learn what are the state-of-the-art solutions to provide access of our BIMS to external stakeholders without compromising security. It would increase the efficiency.

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

9565

#3

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Monday, July 12, 2021 1:23:08 PM
Last Modified:	Monday, July 12, 2021 5:56:19 PM
Time Spent:	04:33:10
Email:	Jean-Claude.Marshall@modernatx.com
IP Address:	173.76.237.102

Page 1

Q1

What type of BIMS do you have?

Internally built (custom solution)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

We use external biorepositories for sample storage. For samples coming in-house for exploratory testing we use an internally built system but are looking at COTS/SaaS vendors; BioFortis and Benchling

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

,

To record sample-related data such as patient demographics or informed consent parameters

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

Internal use will be exploratory R&D purpose. We require a compliant, but not fully validated system. We feel that full validation will limit flexibility.

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Yes

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

For compliance we will use vendor provided documentation for 21 CFR Part 11 and internal documentation for GDPR

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Sample reconciliation and consistently capturing ICF Future Use permissions can be a challenge

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

BIMS allows us to keep track of samples, exploratory use requests, issues and resolutions

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

IT has been very helpful in system evaluations. Biomarker group is looking for ease of use. Adoptions of use need to come from SOP.

Q13

If you are able to overcome any of these challenges, please elaborate how:

We will need Management and IT support, a BIMS administrator, dedicated super-users for each research department, SOPs, communication and training.

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on when to designate a BIMS as a GxP system

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members,

Other (please specify):

TransCelerate

Q16

What other items would you want to be addressed by a BIMS task force?

I think it would be helpful to have a decision tree for evaluating when a system should be validated.

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

7709

#4

COMPLETE

Collector:	Web Link 3 (Web Link)
Started:	Monday, July 12, 2021 5:52:06 PM
Last Modified:	Monday, July 12, 2021 6:01:17 PM
Time Spent:	00:09:11
IP Address:	173.67.5.51

Page 1

Q1

What type of BIMS do you have?

Respondent skipped this question

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

Respondent skipped this question

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To record sample-related data such as patient demographics or informed consent parameters

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

Respondent skipped this question

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Respondent skipped this question

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

Respondent skipped this question

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Respondent skipped this question

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Respondent skipped this question

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

Respondent skipped this question

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

Respondent skipped this question

Q13

If you are able to overcome any of these challenges, please elaborate how:

Respondent skipped this question

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Respondent skipped this question

Q15

Respondent skipped this question

From whom would you prefer to see an output be issued from? Select all that apply:

Q16

Respondent skipped this question

What other items would you want to be addressed by a BIMS task force?

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

5521

#5

COMPLETE

Collector: Web Link 4 (Web Link)
Started: Tuesday, July 13, 2021 4:37:43 PM
Last Modified: Tuesday, July 13, 2021 5:08:44 PM
Time Spent: 00:31:00
IP Address: 98.246.219.97

Page 1

Q1

What type of BIMS do you have?

Commercial off-the-shelf (COTS), Software-as-a-Solution (SaaS)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

BioFortis

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

,

To record sample-related data such as patient demographics or informed consent parameters

,

To record test results from the use of the samples (e.g., name of test run, date of test run, whether valid results were created, test result etc.)

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

Other (please specify):

for projection on upcoming visit dates and sample collections

Q5

How do the use cases for your BIMS affect the amount of validation needed?

System has undergone vendor IQ/OQ upon installation and upgrades. An internal QC of study-specific configuration settings also is conducted for all new studies.

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Yes

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

1) Internally-developed SOP for assessing GxP, SOX and ERES applicability. 2) Reliance on vendor IQ/OQ validation procedures and UAT scripts. 3) Internally-developed study configuration review scripts.

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Gaining a holistic view of all biospecimens in inventory, identifying available specimens for acute testing, projecting future sample availability, reconciling expected sample collections to actual collections, linking EDC sample-related data to specimen inventory, confirming ICF permissions

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

BIMS helps in many of these challenges; however, linking EDC data with sample data continues to be challenging, as does completing sample accounting reconciliation.

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

Use adoption is slower than anticipated. Governance processes are not in place due to lack of bandwidth. System is "owned" by IT, but administered out of the translational research group, so operational investment is a question. Insufficient resources available to build the system for some of clinical ops needs.

Q13

If you are able to overcome any of these challenges, please elaborate how:

Respondent skipped this question

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on how to meet regulatory requirements associated with BIMS

,

Guidance on when to designate a BIMS as a GxP system

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members,

Other (please specify):

potentially ISBER?

Q16

What other items would you want to be addressed by a BIMS task force?

Respondent skipped this question

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

1003

#6

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Tuesday, July 13, 2021 5:45:10 PM
Last Modified:	Tuesday, July 13, 2021 5:58:09 PM
Time Spent:	00:12:59
Email:	delphine.lagarde@roche.com
IP Address:	198.21.24.251

Page 1

Q1

What type of BIMS do you have?

Hybrid (e.g. a customized COTS)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

Lab Vantage

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

,

To record test results from the use of the samples (e.g., name of test run, date of test run, whether valid results were created, test result etc.)

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

Respondent skipped this question

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Yes

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

System is fully validated, we follow all processes of CSV

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Data standardization, data quality (missing or incorrect data)

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

BIMS provides structure that helps with standardization but this is not sufficient. Rules should be established and data governance should be in place

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

None recently, we have been using a BIMS for more than 15 years

Q13

If you are able to overcome any of these challenges, please elaborate how:

Respondent skipped this question

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Respondent skipped this question

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

Respondent skipped this question

Q16

What other items would you want to be addressed by a BIMS task force?

Respondent skipped this question

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

3444

#7

COMPLETE

Collector: Web Link 4 (Web Link)
Started: Thursday, July 15, 2021 11:30:02 PM
Last Modified: Thursday, July 15, 2021 11:52:09 PM
Time Spent: 00:22:06
IP Address: 208.127.232.250

Page 1

Q1

What type of BIMS do you have?

Commercial off-the-shelf (COTS), Software-as-a-Solution (SaaS)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

BioFortis

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To record sample-related data such as patient demographics or informed consent parameters

,

Other (please specify):

Requests for additional testing

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

The fact we receive info from EDC (e.g., ICF info) means a portion of the system is validated.

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Yes

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

We use a validation requirement questionnaire to determine the applicability of 21CFR Part11 and any predicate rules. We also do a GAMP category and system risk level assessment.

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Pushback on collection/storage of samples for additional/future research; reluctance towards tracking of samples that are not used for primary or secondary objectives.

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

BIMS treats all samples equally and removes many of the manual elements of sample tracking.

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

Our BIMS solution is not a LIMS, not EDC, hence somewhat of an unusual product for IT colleagues, putting more pressure on business owners.

Q13

If you are able to overcome any of these challenges, please elaborate how:

Creating a technology focused group within the group overseeing the samples stored in biorepository.

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on determining how to assess validation needs

,

Guidance on when to designate a BIMS as a GxP system

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members

Q16

What other items would you want to be addressed by a BIMS task force?

Respondent skipped this question

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

4099

#8

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Friday, August 06, 2021 12:01:35 AM
Last Modified:	Friday, August 06, 2021 12:33:06 AM
Time Spent:	00:31:30
Email:	diane.leong@gilead.com
IP Address:	35.230.107.0

Page 1

Q1

What type of BIMS do you have?

Commercial off-the-shelf (COTS), Software-as-a-Solution (SaaS)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

BioFortis

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

,

To record sample-related data such as patient demographics or informed consent parameters

,

Other (please specify):

To record assays run on the samples and assay labs but not including the test results

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To coordinate review of subjects' ICF permissions for a potential exploratory research project

,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

The amount of validation is mainly based on the use cases for clinical samples and associated informed consent

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Yes

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

We work with Regulatory Compliance to assess validation requirements

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Clinical operations - needed to align biomarker research needs with their business process and flow of data. Legal - needed to meet legal requirements for GDPR/secondary data use

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

Clinical operations - yes, was able to set up BIMS to handle data flow from their business process. Legal - yes, was able to include data use consent in BIMS

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

Adoption of use of BIMS by some user groups, IT support for archival of data from BIMS legacy systems

Q13

If you are able to overcome any of these challenges, please elaborate how:

User group inclusion in project team and training, guidance/recommendation from compliance group

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on determining how to assess validation needs

,

Guidance on how to meet regulatory requirements associated with BIMS

,

Guidance on when to designate a BIMS as a GxP system

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members,

Other industry body,

Other (please specify):

It would be good to get input from a regulatory authority, however, I think that obtaining their input may take a long time

Q16

What other items would you want to be addressed by a BIMS task force?

Assay lab sample data transfer specifications - many assay labs are not able to provide all the data in the format needed for the BIMS, so that internal mapping/standardization is needed before loading. It might be help to have an industry standard that they need to comply with.

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

1011

#9

COMPLETE

Collector:	Email Invitation 1 (Email)
Started:	Tuesday, August 10, 2021 7:50:18 PM
Last Modified:	Tuesday, August 10, 2021 7:55:25 PM
Time Spent:	00:05:06
Email:	peter.groenen@idorsia.com
IP Address:	94.154.12.132

Page 1

Q1

What type of BIMS do you have?

Internally built (custom solution)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

Respondent skipped this question

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

,

To record sample-related data such as patient demographics or informed consent parameters

,

To record test results from the use of the samples (e.g., name of test run, date of test run, whether valid results were created, test result etc.)

,

Other (please specify):

Also non human samples are being tracked

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

Because we strictly use it for exploratory purposes we consider it not a requirement to validate the system for GxP reasons

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

No

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

Respondent skipped this question

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We conduct our own internal validation procedure.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

None so far

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

Respondent skipped this question

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

None so far

Q13

If you are able to overcome any of these challenges, please elaborate how:

Respondent skipped this question

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on how to meet regulatory requirements associated with BIMS

,

Guidance on when to designate a BIMS as a GxP system

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

I-PWG members,

Regulatory authority

Q16

What other items would you want to be addressed by a BIMS task force?

Respondent skipped this question

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

7820

#10

COMPLETE

Collector:	Web Link 6 (Web Link)
Started:	Tuesday, August 17, 2021 4:55:22 PM
Last Modified:	Tuesday, August 17, 2021 5:06:11 PM
Time Spent:	00:10:49
IP Address:	148.168.96.26

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Q1

What type of BIMS do you have?

Internally built (custom solution)

Q2

If a COTS system (SaaS or self-hosted) or hybrid system, please indicate the vendor:

Respondent skipped this question

Q3

What types of information are you storing within your BIMSs (Biorepository Inventory Management Systems)? Select all that apply:

To track samples collected during the course of a clinical trial

,

To track samples acquired outside clinical trials (e.g., through collaboration with research entities, from tissue brokers, pre-clinical samples, etc.)

Q4

For what purposes (use cases) are you using your BIMS? Select all that apply:

For specimen inventory reporting purposes,

For reconciliation of expected collections,

To identify samples and/or data for secondary exploratory research

Q5

How do the use cases for your BIMS affect the amount of validation needed?

System is GxP validated

Q6

If your system requires any amount of validation, do you have a method for assessing the validation requirements needed?

Yes

Q7

If yes to Question 6, please describe the method you use for assessing the validation requirements:

Vendor (who developed the custom solution for us) has SOPs and practices for developing and maintaining validated systems.

Q8

Do you rely on vendor-conducted validation, do you conduct internal validation, or both? Select one of the following:

We rely on both vendor validation documentation as well as our own internal validation procedures.

Q9

Would you like to know more on how to meet regulatory compliance requirements associated with BIMS, such as GxP regulations, Sarbanes-Oxley Act of 2002, Electronic Records / Electronic Signatures (ERES) (21 CFR Part 11 and EudraLex Annex 11) and General Data Protection Regulation 2016/679?

Yes

Q10

What kind of operational challenges as related to collection/tracking/use of samples and related data have you encountered from working with internal business partners such as clinical operations, medical affairs, regulatory affairs, legal and compliance groups?

Buy-in for the need of BIMS, adoption in the use of BIMS, implementation of governance processes, etc.

Q11

Does BIMS help you overcome any of these challenges? If yes, please elaborate:

N/A

Q12

What kind of BIMS-related challenges (e.g., buy-in for the need of a BIMS, adoptions in the use of BIMS, implementation of governance processes, etc.) have you encountered from working with internal business partners such as IT, clinical operations, and compliance groups?

See above

Q13

If you are able to overcome any of these challenges, please elaborate how:

N/A

Q14

What type or format of output would you like to see come out of a BIMS-related Task Force? Select all that apply:

Guidance on how to meet regulatory requirements associated with BIMS

,

Guidance on when to designate a BIMS as a GxP system

Q15

From whom would you prefer to see an output be issued from? Select all that apply:

Regulatory authority

Q16

What other items would you want to be addressed by a BIMS task force?

One area not directly related to compliance/validation would be the development of industry standards around the transmission of specimen-related metadata to facilitate the exchange of information across different BMISs.

Q17

Finally, can you please provide the individual Survey Monkey code that has been provided to you by Julian Arbuckle:

2772