PRECISION quartzbio®

6 Critical Discrepancy Reports for Sample & Biomarker Operations

Do you have a 360° view of your clinical sample ecosystem to catch discrepancies across systems? Keep your top reports at your fingertips for efficient operations.

Clinical operations, biospecimen management and translational science leaders use a variety of reports to gain visibility across their data. Traditionally, generating these reports is frustratingly time-consuming – often involving spreadsheets that attempt to manually link key information from the EDC, central labs, testing labs, and biorepositories to illuminate critical information like discrepancies or missed collections.

The QuartzBio® team has identified six critical on-study reports that our clients prioritize as absolutely required for effective sample and biomarker operations. Coupled with generating the reports continuously throughout the life of a study, our clients reiterate the need for teams to have collaborative visibility as new data are available.

In this quick guide, we highlight these six key reports – and introduce QuartzBio's AI-enabled Biomarker Intelligence Platform that powers them.

- Missing Samples Report
- Samples with Potential Consent Violations
- Subject IDs in Unrecognizable Formats
- Missing Collections/Data Entry Errors
- Collection Dates Missing from Sample Inventroy
- Samples with Discrepant Sample Collection Entries (EDC vs. Inventory)

Report One

Missing Samples Report

Knowing the difference between collected samples and expected samples can make or break data generation plans: are you proactively surfacing collection anomalies?

Clinical operations teams must extract information from multiple sources, including protocols, protocol revisions, and optional consent forms, to gain visibility into what samples and derivatives are expected to be collected. Teams then compare these expectations to actual collection data. The resulting report can be tedious to generate. With a dynamic dashboard, like in the QuartzBio® vSIM product, the missing samples report is easy to access, filter, and share, saving clinical operations teams time and providing opportunities to intervene during the trial to minimize loss of critical specimens and data.

5.3 Difference between Collected/Available and Expected Samples/Derivates

The following tables shows expected collection units per the sample schedule where units are missing or collected extra. Positive unites in the last column indicate extra units,negative units indicate missing units.

NOTE: To reduce the number of queries, the number of units to be collected was not taken into account for reporting gaps in sample collection, i.e. only instances where samples were completely missing are reported; however, samples were insufficient amount were collected are not reported.

5.3.1 Overall

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Collection group	Subject ID	Sample Type	Collection Timepoint	Expected	Collected	Missing/Extra
ALL	ALL	ALL	ALL	ALL	ALL	ALL
4	101-02	WHOLE BLOOD	BL/D1	3	0	-3
4	107-10	BIOPSY	BL/D1	1	0	-1
4	106-02	PLASMA_PD	W4/D26	3	0	-3

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Report Two

Samples with Potential Consent Violations

Don’t risk non-compliance with error-prone consent management methods.

When managing complex sample inventories across labs and repositories, clinical teams often spend time manually cross-referencing inventory data with informed consent forms and protocols.

With a dynamic dashboard, you can review the protocol under which each subject was enrolled, as well as consent forms. In addition to discrepancies in expected sample collection, you can also detect and report instances where a sample was collected, but optional consent was not given.

In this example, the study has two optional consents, for genetic testing and biopsy sampling. In this report, three subjects did not consent to biopsy, but a biopsy was taken, violating consent.

4.6 Samples with Invalid Collection Based on Consent

The following tables lists 1 samples/derivatives where DNA or biopsy samples were collected when the subject had not consented to those collections per the clinical eCRF information

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DATA_SOURCE 1	SUBJID	C101_DATE	DERIVATIVED	SAMPLE TYPE	TPT	COLLECTION_DATE	GENETIC_CONSENT	BIOPSY_CONSENT	BIOPSY_CONSENT
LAB 1	106.02	2015-10-24	WD020027 0001	BIOPSY	BL/D1	2015-10-24	NO	NO	BIOPSY
LAB 1	106.14	2019-10-24	WD020034 0001	BIOPSY	W12D84	2020-04-13	NO	NO	BIOPSY
LAB 1	106.34	2019-10-24	WD020104 0004	BIPOSY	BL/D1	2019-10-24	NO	NO	BIOPSY

Showing 1 to 3 of 3 entries

Missing Samples Report

Samples with Potential Consent Violations

Subject IDs in Unrecognizable Formats

Missing Collections/Data Entry Errors

Collection Dates Missing from Sample Inventroy

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Report Three

Subject IDs in Unrecognizable Formats

Flag formatting mistakes – they're just a keystroke away.

Pulling together sample inventories and metadata across sites, central, and testing labs is already a tedious task. Subject IDs that do not match the expected format prevent accurate reporting. Clinical teams frequently use the "Problematic Subject IDs" report in QuartzBio® vSIM to quickly address these discrepancies.

4.1 Problematic Subject IDs

The following subject IDs are erroneous and need to be corrected as they do not conform with expected format of a 3 digit site identifier and a 2 didgit site-specific subject identifier:

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DATA_SOURCE 1	SUBJID	SAMPID	TPT	SAMPLE TYPE	COLLECTION_DATE
LAB 1	12-102	WD020299	W12/D84	PLASMA_PD	2020-03-16
LAB 2	36-104	WD24740	W16/D104	PLASMA_PD	2020-04-20
LAB 1	18-102	WD019406	W16/D104	PLASMA_PD	2020-04-20
LAB 3	21-102	WD019081	W20/D136	PLASMA_PD	2020-04-16

Showing 1 to4 of 4 entries

Missing Samples Report

Samples with Potential Consent Violations

Subject IDs in Unrecognizable Formats

Missing Collections/Data Entry Errors

Collection Dates Missing from Sample Inventroy

Samples with Discrepant Sample Collection Entries (EDC vs. Inventory)

Report Four

Missing Collections/Data Entry Errors

Detect errors introduced from multiple touchpoints.

Samples without a recorded collection date in the electronic data capture (EDC) could either indicate a data entry error or, potentially, that a sample without a recorded collection in the EDC was received by the central or specialty lab. The latter could indicate a more serious issue at the site. With multiple labs and biorepositories, there are multiple points at which these errors can occur.

This QuartzBio® vSIM report lists samples whose collection date is more than 14 days prior to the last EDC export.

4.3 Samples with Missing EDC Collection Dates

The following table lists 2 samples/derivatives with missing EDC entries. A sample was identified as missing if the sample collection date was more than 14 days prior to the last EDC export. The last EDC expoert was obtained on 2020-02-14 and thus any samples with collection dates before 2020-01-31 were considered to be lacking expected EDC entries.

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DATA_SOURCE	SUBJID	SITEID	SAMPID	DERIVATIVID	TPT	SAMPTYPE	COLLECTION_DATE	EDC_COLLECTION_DATE
LAB 1	106-02	106	WD020227	WD020027 0001	BL/D1	BIOPSY	2019-10-24	
LAB 1	122.02	122	WD021110	WD020110 0001	BL/D1	BIOPSY	2020-01-13	

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Report Five

Collection Dates Missing from Sample Inventory

Surface inventory issues, such as with accessioning or shipping.

Sometimes, the electronic data capture is complete, but the inventory provided by a lab or repository is missing the corresponding collection data. This could occur where samples were either not accessioned properly, or where a given sample was never received. The ability to maintain continuous visibility, like the visibility provided by QuartzBio® vSIM, enables teams to address discrepancies before more serious issues occur.

4.3 Samples with Missing Collection Dates

The following table lists 15 samples/derivatives are missing collection date(s) in the lab inventories

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DATA_SOURCE	SUBJID	SITEID	SAMPID	DERIVATIVID	TPT	SAMPTYPE	COLLECTION_DATE	EDC_COLLECTION_DATE
ALL	ALL	ALL	ALL	ALL	ALL	ALL	ALL	ALL
LAB 1	131-08	131	WD020457	WD020457 0050	BL/D1	WHOLE BLOOD		2020-04-01
LAB 1	131-08	131	WD020457	WD020457 0300	BL/D1	PLASMA_PK		2020-04-01
LAB 1	131-08	131	WD020457	WD020457 0500	BL/D1	PBMC		2020-04-01
LAB 1	131-08	131	WD020457	WD020457 0501	BL/D1	PBMC		2020-04-01
LAB 1	131-08	131	WD020416	WD020457 0516	BL/D1	Plasma_PK		2020-03-05
LAB 1	131-08	131	WD020416	WD020457 0517	BL/D1	PLASMA_PK		2020-03-05
LAB 1	131-08	131	WD020416	WD020457 0301	BL/D1	PBMC		2020-03-05
LAB 1	131-08	131	WD020416	WD020457 0050	BL/D1	WHOLE BLOOD		2020-03-05

Showing 1 to 10 of 15 entries

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Report Six

Samples with Discrepant Sample Collection Entries

Streamline reconciliation between EDC and multiple inventories.

This report shows direct reconciliation issues between the electronic data capture (EDC) and inventories at central labs, specialty labs, and biorepositories. The QuartzBio® vSIM SaaS product is designed to streamline and automate reconciliation, a time-consuming process that is typically manual and requires accessing multiple systems.

4.5 Samples with Discrepant Sample Collection Entries

The following table lists 76 samples/derivatives with discrepancies between inventory and EDC entries in sample collection dates vs. EDC visit dates.

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DATA_SOURCE	SUBJID	SITEID	DERIVATIVID	TPT	SAMPTYPE	COLLECTION_DATE	EDC_COLLECTION_DATE	EDC_VISIT_DATE	DISCREPANCY
ALL	ALL	ALL	ALL	ALL	ALL	ALL	ALL	ALL	ALL
LAB 1	131-08	WD020234	WD020457 0050	W12/D84	WHOLE BLOOD	2020-04-01	2020-04-01	2020-04-12	EDC CALL/VISIT DATE DISC.
LAB 1	131-08	WD020234	WD020457 0300	W12/D84	PLASMA_PK	2020-04-01	2020-04-01	2020-04-19	EDC CALL/VISIT DATE DISC.
LAB 1	131-08	WD020234	WD020457 0500	W12/D84	PBMC	2020-04-01	2020-04-01	2020-04-01	EDC CALL/VISIT DATE DISC.
LAB 1	131-08	WD020234	WD020457 0050	W12/D84	PLASMA_PD	2020-04-01	2020-04-01	2020-04-14	EDC CALL/VISIT DATE DISC.
LAB 1	131-08	WD020234	WD020457 0300	W12/D84	WHOLE BLOOD	2020-04-01	2020-04-01	2020-04-01	EDC CALL/VISIT DATE DISC.
LAB 1	131-08	WD020234	WD020457 0500	W12/D84	PLASMA_PK	2020-04-01	2020-04-01	2020-04-21	EDC CALL/VISIT DATE DISC.
LAB 1	131-08	WD020234	WD020457 0500	W12/D84	PBMC	2020-04-01	2020-04-01	2020-04-26	EDC CALL/VISIT DATE DISC.

Showing 1 to 10 of 15 entries

Missing Samples Report

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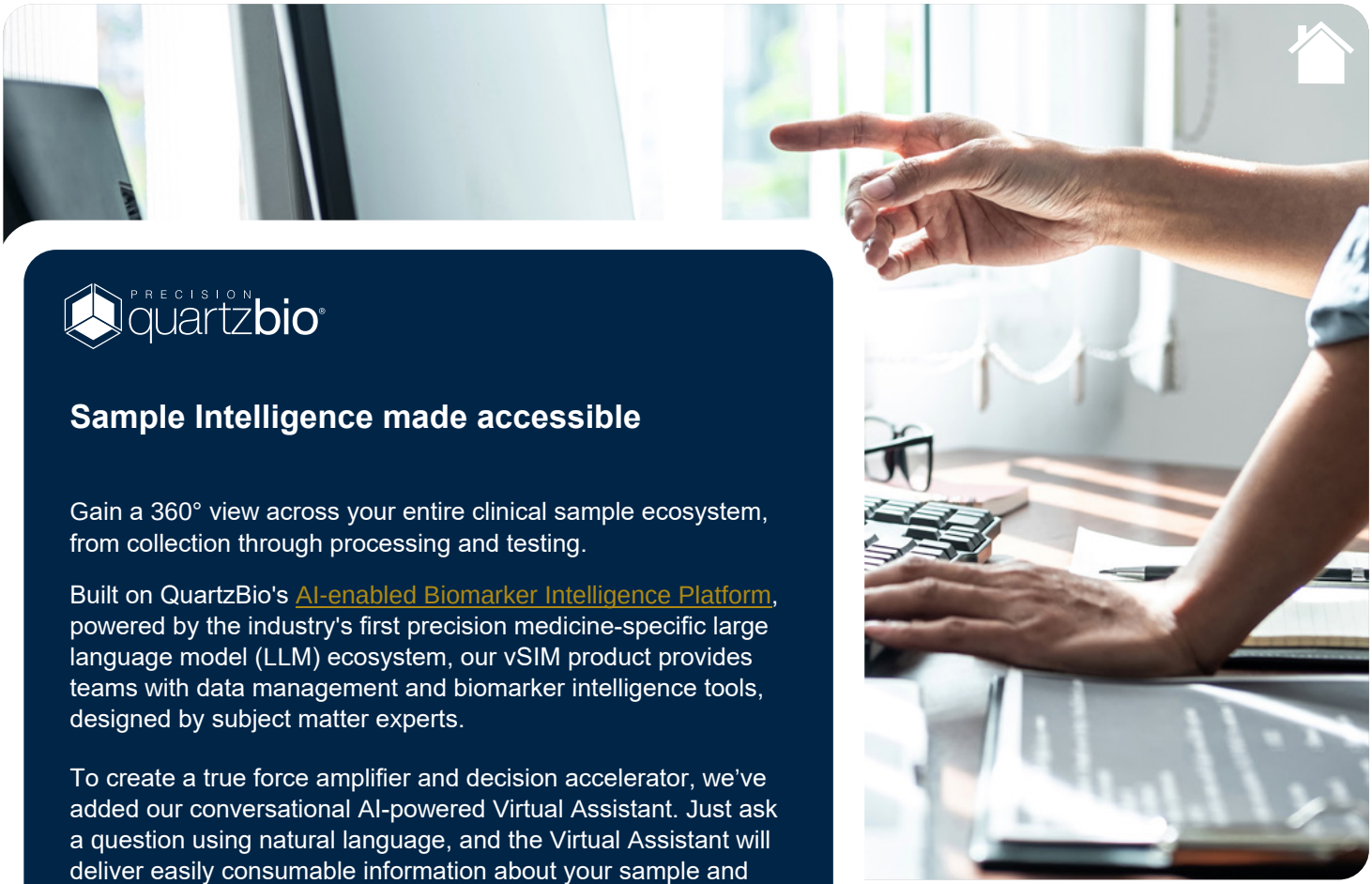
Collection Dates Missing from Sample Inventroy

Samples with Discrepant Sample Collection Entries (EDC vs. Inventory)



PRECISION quartzbio®

Sample Intelligence made accessible

Gain a 360° view across your entire clinical sample ecosystem, from collection through processing and testing.

Built on QuartzBio's AI-enabled Biomarker Intelligence Platform, powered by the industry's first precision medicine-specific large language model (LLM) ecosystem, our vSIM product provides teams with data management and biomarker intelligence tools, designed by subject matter experts.

To create a true force amplifier and decision accelerator, we've added our conversational AI-powered Virtual Assistant. Just ask a question using natural language, and the Virtual Assistant will deliver easily consumable information about your sample and biomarker data in seconds.

To learn more about how precision medicine development teams are using vSIM and the AI Virtual Assistant visit us at www.quartzbio.com.

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