



IQVIA Biobanking

GCloud 15 Service Definition

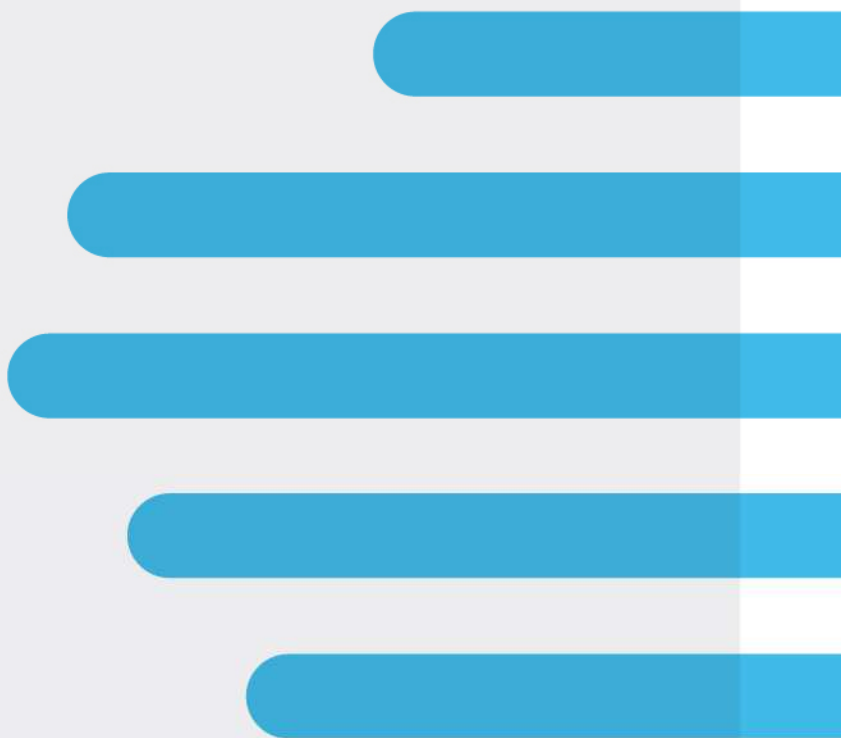


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IQVIA BIOBANKING SOLUTION

The IQVIA Biobanking solution is part of a modular research-centric software suite, the IQVIA Health Data Research Platform (HDRP) that provides a wide range of functionality and orchestrated processes for reliable and well documented biospecimen management and research in general. HDRP modules include the Biobanking solution described in more detail here, as well as a Study Register with Trial Matching, a Clinical Trial Management System (CTMS), a Meta Data Repository, a Raw Data Archive, and a Patient App. Clients can start small, and scale as needed and utilise several API technologies to integrate into existing IT infrastructures (e.g., FHIR, HL7, XML, IHE, CDISC-ODM, OMOP, etc.).

HDRP clients own and host their solutions on hardware of their choice (either on-premises or in the cloud). All data that is collected in the solution belongs to the client. IQVIA will support with Maintenance of the software (e.g., by provisioning bugfixes) and provide support on how to backup, restore, and implement disaster recovery plans. The Biobanking solution can run on MSSQL, Oracle, or PostgreSQL databases. These belong to the client and can be freely accessed upon exit. The solution can also be implemented with an XML/REST interface that allows import and export of all relevant data from the solution.

Background & Philosophy

HDRP solutions have been on the market for over fifteen years. In 2008, HDRP was created by a spinoff of the Charité University Medicine in Berlin, one of the largest university hospitals in Europe. It was clear the current state of clinical research was far from where it should be, and the HDRP team wanted to do its part to help create a paradigm shift towards personalised medicine.

The initial focus began with supporting biobanks in their day-to-day operations. The resulting IQVIA Biobanking solution includes the ability to ingest legacy data from systems that need to be retired, as well as the API technology to establish a data integration platform for all data relevant to the biospecimens and their donors. The solution permits managing user access rights and offers out of the box workflows for manual data capture around the registration, processing, storage, as well as destruction/shipment/analysis of biospecimens. All biospecimen data can be stored in donor records that can contain longitudinal clinical history data when available (e.g., all relevant diagnostic, and therapeutic events). Consent provided by the donors can also be linked, ensuring that all actions carried out are compliant with the donor's wishes. Device integration was also key for biobanks with higher throughputs. The HDRP team has continued to build out client-specific interfaces and integrations to devices such as liquid handling platforms (e.g., Hamilton), quantifiers (e.g., NanoDrop), automated/smart storage units (e.g., Hamilton/Brooks), flatbed scanners (e.g., FluidX, ThermoScientific, Ziath, etc.), as well as other equipment (including label printers and handheld scanners). Specimen data always maintains the full chain of custody. All specimens can be visualised in a hierarchical structure (i.e., children specimens resulting from processing an original master specimen are displayed in a tree structure within each donor's specimen tab). Data collected on specimens consist of standard data fields in the solution

(e.g., specimen kind, volume, specimen container, specimen location, 1-n configurable Specimen IDs, etc.). In addition, any number of data fields can easily be built by the client via the user interface. Each parameter set up in the system receives a unique name and code, is registered as a specific data type [e.g., Boolean, string, date, single selector, multi selector, file upload field, etc.] and is grouped into forms that can be used for manual data capture or data ingestion from other source systems in time-stamped findings (e.g., blood analytes, quality reports, etc.). This allows our clients to independently set up and manage their own forms for capturing any structured datapoints they require on specimens/donors/storage locations/devices/projects, etc. No programming skills are required for this configuration of the system.

All data stored in the Biobanking application, including those from the data points the clients defined themselves, can quickly be searched by end users through a query interface. All search criteria can be grouped with comparison and logical operators (</>/AND/OR, etc.). Users can thus quickly build complex queries to help identify specific donors and/or their specimens. Queries can be saved and shared with other users. Result tables are configurable and can be exported as PDF or CSV files. In addition, entries from the result lists can be moved into specimen lists that can be used for batch processing (e.g., removal and shipment).

To support growing client needs, HDRP system architecture allows for flexibility with the integration of workflow and reporting engines. These allow mapping out of client-specific standard operating procedures (SOPs) into system-driven, highly customised workflows that can be executed by end users with appropriate access rights. Furthermore, IQVIA offers training to its clients' IT personnel to allow them to develop these components themselves. The same goes for the ability to access available APIs (XML/REST) to build new interfaces, as well as best practices on how to back up the database, test disaster recovery, manage access rights settings, and much more.

In addition to being used as a Biobank Management tool, the HDRP team has continued to build out module extensions to create synergies. These modules include a Study Register with Trial Matching, a Clinical Trial Management System with an eCRF designer, a Meta Data Repository, a Raw Data Archive, an OMOP Pipeline, and a Patient App.

HDRP was built in Germany and has a proven track record, currently installed in 32 of 38 university hospitals in Germany, 4 out of 6 Health Centres, and used by The National Cohort, Germany's largest epidemiological study, which stores more than 40 million biospecimen records in its IQVIA Biobanking Solution. Over the last decade, IQVIA has further expanded in Europe with HDRP solutions, which are currently in use in Austria, Switzerland, Slovenia, the UK, Italy, Czech Republic, Spain, and North America (Canada, and United States).

Overview of Features and Benefits

Extract of Key Features:

- Aggregation of relevant source data into longitudinal patient/donor records (e.g., therapeutic, and diagnostic events).
- User-friendly, high-quality data collection workflows regarding biospecimen collection/processing/shipment/analytics (incl. references to SPREC code).
- Storage location management (design of location hierarchies, e.g., freezer->compartment->box->box position)
- Seamless integration of devices for support of high-throughput workflows (e.g., flatbed scanners, pipetting robots, automated freezers)
- Query interface for quick/complex searches of patient/biospecimen cohorts
- User management (incl. detailed rights & roles management)
- Pseudonymisation algorithms
- Configurable forms designer

Extract of Key Benefits:

- Improve collaboration across departments with one centralised biobank management system.
- Improve quality of biospecimen data
- Reduce time needed for the request and provision of access to biospecimen data and the biospecimens themselves.
- More easily comply with regulations (e.g., by linking consent data to the biospecimen records).
- Create more accurate reports of sample inventory in less time.
- Raise quality of biospecimen data by contextualising with donor's clinical data.
- Orchestrate/parallelise processes to improve productivity with integrated workflow engine

Contact IQVIA

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