FAQ firstbase

Webinar Swiss Medtech / GS1 Switzerland

February 28th, 2023

Question	Answer
General questions	
What is about HCI Database? Integration planned?	firstbase healthcare is in its first version primarily intended for Medical Devices. Pharmaceutical products are not in the scope of the solution.
Will products from Med classes 1 to 3 follow?	firstbase healthcare supports all kind of Medical Devices such as MDR risk classes 1 - 3, low - high risks In-Vitro Diagnostics, as well as MDD, IVDD and AIMDD.
Also, IVD products can be included?	Yes, firstbase healthcare supports all kind of Medical Devices, including IVD products.
Who Feeds in the data? Manufacturer or Importer?	firstbase healthcare follows the principles "from the source" and "once-only". Therefore, the data are filled in by the data owner or the authorized representative. That could be the manufacturer, the importer, and/or the CH-representative.
What is the advantage of your solution compared to other data exchange platform solutions?	firstbase healthcare impresses with several points. It shows the data "from the source", according to the "once-only principle", and as the industry solution for the Swiss healthcare system, will optimize processes but also resources in the long term. firstbase was developed in close cooperation with the members (sender/recipient) and thus precisely meets the requirements. Set up and hosted by GS1 Switzerland, under the neutral, member-driven umbrella of the not-for-profit association GS1 Switzerland, the solution is developed closely with its members for members.

Who will make sure that as much content as possible will be on firstbase as soon as possible?	In order for as much data as possible to be entered into firstbase healthcare as quickly as possible, the community support is needed. On the one hand, we need the data senders to share data via firstbase, and on the other hand, we need the data recipients such as hospitals, clinics, laboratories etc. who receive and utilize the data. Every party, every stakeholder in this ecosystem can make a valuable contribution and establish firstbase as the Swiss industry solution.
Can you provide references from medical device companies that have converted to your system?	The following companies have already populated their product master data to firstbase (Feb 28, 2023): B. Braun Medical AG, Johnson & Johnson, Medtronic, Roche Diagnostics Schweiz AG, Cosanum, Mathys Medical AG.
How are data from a manufacturer and from an importer matched (also in case of mismatch)?	It is the responsibility of the information provider to supply timely, accurate and complete data. If discrepancies are detected, various mechanisms are available to prompt for correction of the data.
How is data controlled? Does manufacture have to log into firstbase and send the data to the different regulatory database?	Data senders - after initial registration - maintain their data through one of the various channels (API, Web-UI, data upload) in firstbase and publish it to a central catalogue. For the regulatory databases the data might be enriched with their specific needs and published through a validated connector, or GDSN where possible (e.g., GUDID). These connectors can be licensed additional.
If an importer enters a GTIN into firstbase, that has already been entered by a CH-REP, will the attributes sync automatically, or will there be two different	firstbase healthcare follows the principles "from the source" and "once-only". Therefore, the data are filled in by the data owner or the authorized representative. That could be the manufacturer, the importer, and/or the CH-representative. Existing data might be utilized for this.
I assume firstbase will be able to manage UDI not issued by GS1 as well, correct?	In firstbase healthcare, medical devices with other identifiers such as ICCBBA or HIBIC can also be maintained. However, the primary ident is the GTIN. This means that a product with i.e., a HIBIC code must also be maintained with a corresponding GTIN.

What is the difference with GS1 Atrify?	firstbase establishes an industry solution for the Swiss healthcare system. Accompanied and supported by the steering committee of medical device manufacturers (Swiss MedTech), hospitals (H+), the foundation for the identification of organizations and individuals in the Swiss healthcare sector (refdata) and GS1 Switzerland, the platform is set up and hosted under the neutral, member-driven umbrella of GS1 Switzerland which operates as a not-for-profit organization for its members.

Regulatory related questions	
Is firstbase a validated system? Has firstbase had any success in consolidating disparate data attributes amongst the various associations and systems you plan to share data with?	firstbase healthcare is based on the GS1 Switzerland data platform with its GDSN certified data pool. All requirements have been gathered and aligned during the use case project phase with key stakeholders from industry, reseller and hospitals. Accompanied and supported by the steering committee of medical device manufacturers (Swiss MedTech), hospitals (H+), the foundation for the identification of organizations and individuals in the Swiss healthcare sector (refdata) and GS1 Switzerland, firstbase shall be established as the industry solution for the Swiss healthcare system.
Is my understanding correct that later, the Swissdamed will be working through firstbase?	Regulatory databases such as EUDAMED or GUDID can be served via firstbase. GS1 Switzerland maintains close contact with Swissmedic and aims to reach Swissdamed via firstbase. This means that data senders can maintain their data in firstbase and then share it with Swissdamed.
What will be the connection of this platform with the upcoming SWISSDAMED?	firstbase will be connected to swissdamed with a connector. This means that data senders can maintain their data in firstbase and then share it with Swissdamed.
And with EUDAMED?	Regulatory databases such as EUDAMED or GUDID can be served via firstbase.
How do you handle the different challenges of the UDI databases? Do you have a technical connection to the global UDI databases?	With our solution provider Bayard, we can provide a connector to all major regulatory databases. This allows data to be maintained in firstbase and then sent to the various databases. The various connectors take care of the mapping, the fulfilment of the requirements and ensure that the data is transmitted correctly.

Since I already chose the connector e.g. EUDAMED and SwissMed, will these databases automatically be updated when my data changes or do I have to choose the connector again?	Data senders maintain their data in firstbase, ensuring that the data is up to date. When changes are made to product master data, the data is updated the central catalogue and, if relevant also synchronized with the regulatory databases.
How are you handling the differences in requirements, editability, picklist values between the different regulators and customers? These are not harmonized into one model.	Depending on the target recipient (firstbase healthcare catalogue, GDSN recipient, e.g., in other target markets or regulatory databases), the data set and requirements differ. For the regulatory databases dedicated enrichment might be needed and rules to be followed.
Can you please share information to which Regulator UDI databases firstbase connects today for UDI data submission. Is there an area where I can find Information on the current state?	With firstbase you can reach major regulatory databases such as GUDID, EUDAMED, as well as NHS or LIR.
But the Profiles does not cover the Regulatory Databases	firstbase healthcare supports the major Regulatory Databases like EUDAMED, GUDID, NHS, etc. However, their requirements are not necessarily part of the Swiss healthcare profile and thus not included in the Swiss profiles overview document.
Are you planning to connect to EUDAMED thought GDSN or do you have another data model for EUDAMED?	GDSN cannot fully support EUDAMED due to its specific structure. firstbase offers an EUDAMED connector: already maintained data shall be enriched with EUDAMED specific requirements and is then shared via the connector with EUDAMED. This connector can be licensed additional.
Can firstbase translate attributes according to business rules relevant for databases before data exchange to these databases?	firstbase healthcare supports the major Regulatory Databases like EUDAMED, GUDID, NHS, etc. (swissdamed is planned) depending on the Database needs via GDSN or a dedicated connector: already maintained data shall be enriched with specific requirements. Rules and translation ensure the accuracy, completeness and conformity of the data and the requirements.

Data fields and attributs

Where do I find the specification for the DataFields that are mandatory / optional?	You'll find the actual GS1 Swiss Profiles Overview - (FEB23) on our website: https://www.firstbase.ch/de/plattform This document, allows you to easily filter by the requirements for the Swiss healthcare community, or search for attributes or attribute groups. Each attribute is specified with definition, its status (mandatory, optional, conditional), format, valid values. In addition, it contains information on rules and dependencies, as well as a link to the code list (pick list) where applicable. This helps you to fill in the attributes.
Are you going to implement a standard of "must" master data for a products which will be uploaded to the platform?	You'll find the actual GS1 Swiss Profiles Overview - (FEB23) on our website: https://www.firstbase.ch/de/plattform This document, allows you to easily filter by the requirements for the Swiss healthcare community, or search for attributes or attribute groups. Each attribute is specified with definition, its status (mandatory, optional, conditional), format, valid values. In addition, it contains information on rules and dependencies, as well as a link to the code list (pick list) where applicable. This helps you to fill in the attributes. The aligned attribute scope is completely implemented. Several additional rules and validations will be rolled out with the May release, since the global healthcare community has committed itself to only one release per year. This approach enables the global data suppliers to exchange their GDSN data directly today, as is, and complete e.g., certification information after the May release while suppliers directly connected to firstbase can populate all requested attributes already, including new data such as certification information details. In several workshops, data senders as well as data recipients agreed on the current profile and the implementation approach. The community will continuously work on future requirements. This work in turn has an influence on the profile in firstbase.

Pricing related questions

What are the costs for the "Data Provider" to be part of the firstbase community?	To use firstbase you need on one hand side a license. This license is based on an annual fee. On the other side you will also need a membership with GS1 Switzerland. Then you can choose different variants which suit you best. On https://www.firstbase.ch/de/plattform/angebot you will find a price overview as well as a price calculator. We will be happy to help you if you are unsure.
Why doesn't the fee scale with the number of entries? A company selling one product pays the same as a company selling 10 products	When defining the prices, GS1 Switzerland made sure that the billing of the sales levels was kept simple and transparent.

Here you find more information:

Stay up to date - Sign up for the **newsletter firstbase** at https://www.firstbase.ch/de/startseite-firstbase/newsletter

Would you like to become part of the solution and register for firstbase right away? Click here to go directly to the **registration** https://www.firstbase.ch/de/plattform/angebot/firstbase-wizzard

Want to learn more about **pricing** first? Calculate your costs here: https://www.firstbase.ch/de/plattform/angebot

Arrange a **personal meeting** at GS1 Switzerland https://www.firstbase.ch/de/kontakt-0

For all further information visit the **website** www.firstbase.ch

Thank you very much for your interest!