Title page

Title: Development of interoperable, domain-specific extensions for the German Corona Consensus (GECCO) COVID-19 research dataset using an interdisciplinary, consensus-based workflow

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Abstract

Background

The COVID-19 pandemic has spurred large-scale, inter-institutional research efforts. To enable these efforts, researchers must agree on dataset definitions that not only cover all elements relevant to the respective medical specialty but that are also syntactically and semantically interoperable. Following such an effort, the German Corona Consensus (GECCO) dataset has been developed previously as a harmonized, interoperable collection of the most relevant data elements for COVID-19-related patient research. As GECCO has been developed as a compact core dataset across all medical fields, the focused research within particular medical domains demands the definition of extension modules that include those data elements that are most relevant to the research performed in these individual medical specialties.

Objective

To (i) specify a workflow for the development of interoperable dataset definitions that involves a close collaboration between medical experts and information scientists and to (ii) apply the workflow to develop dataset definitions that include data elements most relevant to COVID-19-related patient research in *immunization*, *pediatrics,* and *cardiology.*

Methods

We developed a workflow to create dataset definitions that are (i) content-wise as relevant as possible to a specific field of study and (ii) universally usable across computer systems, institutions, and countries, i.e., interoperable. We then gathered medical experts from three specialties (*immunization*, *pediatrics,* and *cardiology*) to the select data elements most relevant to COVID-19-related patient research in the respective specialty. We mapped the data elements to international standardized vocabularies and created data exchange specifications using HL7 FHIR. All steps were performed in close interdisciplinary collaboration between medical domain experts and medical information scientists. The profiles and vocabulary mappings were syntactically and semantically validated in a two-stage process.

Results

We created GECCO extension modules for the *immunization*, *pediatrics,* and *cardiology* domains with respect to the pandemic requests. The data elements included in each of these modules were selected according to the here developed consensus-based workflow by medical experts from the respective specialty to ensure that the contents are aligned with the respective research needs. We defined dataset specifications for a total number of 48 (*immunization*), 150 (*pediatrics*), and 52 (*cardiology*)

data elements that complement the GECCO core dataset. We created and published implementation guides and example implementations as well as dataset annotations for each extension module.

Conclusions

These here presented GECCO extension modules, which contain data elements most relevant to COVID-19-related patient research in *immunization*, *pediatrics* and *cardiology*, were defined in an interdisciplinary, iterative, consensus-based workflow that may serve as a blueprint for the development of further dataset definitions. The GECCO extension modules provide a standardized and harmonized definition of specialty-related datasets that can help to enable inter-institutional and cross-country COVID-19 research in these specialties.

77 ## Keywords

78 - COVID-19
79 - Interoperability
80 - GECCO dataset
81 - FHIR
82 - Research dataset
83 - FAIR principles

84

Introduction

The COVID-19 pandemic has led to unprecedented strong efforts in connecting nationwide and international research to help in managing the disease and its effects on public health. To enable research across different health care providers, institutions or even countries, interoperability between the medical data systems is essential [1]. Therefore, early in the pandemic, the German Corona Consensus Dataset (GECCO) has been developed in a collaborative effort to provide a standardized, unified core dataset for inter-institutional COVID-19-related patient research [2]. The GECCO dataset specifies a set of 81 essential clinical data elements from 13 domains such as anamnesis & risk factors, symptoms, and vital signs, that have been selected by expert committees from university hospitals, professional associations, and research initiatives. Since its development, the GECCO dataset has been implemented in a large number of institutions, most notably in virtually every German university hospital, which now provides access to the GECCO dataset in the context of the German COVID-19 Research Network of University Medicine ("Netzwerk Universitätsmedizin") [3,4].

The GECCO dataset has been developed to contain as many relevant data elements as possible, but few enough to keep the effort of implementing the dataset manageable. Therefore, the dataset contains mostly data elements of general research interest, excluding data elements that are only of interest for particular medical specialties or use cases. These data items are considered part of domain-specific extension modules to the GECCO dataset, which are introduced in this article.

Thus, we here aimed to develop domain-specific extensions to the GECCO dataset that cover the most relevant data elements for COVID-19-related patient research for the medical specialties of *immunization*, *pediatrics,* and *cardiology*. To that end, we first developed a workflow that aims at providing dataset definitions that (i) contain the most relevant data elements for the research aims of the end users and (ii) that can be applied universally across institutions and countries. We then followed that workflow with different groups of medical experts from different medical specialties to define extension modules relevant for *immunization*, *pediatrics,* and *cardiology.*

These extension modules complement the GECCO core dataset and use the same international health IT standards and terminologies as the GECCO dataset, such as the *Systematized Nomenclature of Medicine - Clinical Terms* (SNOMED CT)[5] and *Logical Observation Identifiers Names and Codes* (LOINC)[6,7] and the *Fast Healthcare Interoperability Resources* (FHIR)[8,9] standard. The extension modules were developed in close alignment with the GECCO dataset to ensure interoperability and compatibility with existing definitions.

We here describe the consensus-based data element selection and data format definition workflow that we applied in close collaboration between medical experts from *immunology*, *pediatrics,* and

cardiology domains on the content definition side and medical information specialists and FHIR developers on the technical side. This workflow may serve as a blueprint for further development of consensus-based data set definitions.

Methods

Workflow definition

We aimed to develop a workflow to create dataset definitions that are (i) content-wise as relevant as possible to a specific field of study and (ii) universally usable across computer systems, institutions, and countries, i.e., interoperable. We based the specification of the workflow on our experience with the definition of the German Corona Consensus (GECCO) dataset, where health professionals from 50 institutions (university hospitals, professional associations and other relevant organizations) participated to define the most relevant data elements for general scope COVID-19-related research [2]. To fulfil the first requirement (relevancy), we decided to leave the full responsibility of data element selection to groups of medical professionals of the respective specialty, with only minimal interference by the development team. We have deliberately left the exact process open of how the group of medical experts may select the data elements (e.g., literature review, focus groups, consensus-based processes) to allow maximal flexibility of the dataset definition workflow with respect to the medical experts' values and preferences. To fulfil the second requirement (interoperability), we adopted a model loosely based on Jacobsen's workflow for data FAIRification [10], with mapping, quality assurance and publication steps as outlined in detail below.

Selection of data items

The content of the domain-specific research datasets was defined by medical domain experts in a transparent workflow (Figure 1). The involvement of the medical domain experts as the end-users of the data to be provided ensured that the contents of the datasets are aligned to the actual research needs. In our project, the so-called subject- and organ-specific working groups of the national pandemic cohort net (NAPKON) served as the domain-specific groups of medical experts. These groups were established by voluntary association of medical experts from the respective medical specialty in the context of the nationwide NAPKON project in Germany. Each of the subject- and organ-specific working groups elected a board, and all communication between the dataset developers and the working groups was organized and carried out via the working groups' board. In preparation for the GECCO extension modules, we invited the subject- and organ-specific groups for *immunology*, *pediatrics* and *cardiology* to provide up to 50 data elements with up to 10 response items each that were, in the view of the medical experts, the most relevant data elements to patient-related COVID-19 research in their medical specialty and that were not already included in the GECCO core dataset.

If necessary, more data items or response options could be provided in coordination with the development team. The provided data items were then reviewed by the development team and a first definition of the contents of the extension module was returned to the respective subject- and organ-specific working group for approval or change requests. After approval by the subject- and organ-specific working group, the definition of the extension module content was considered finalized.

Development of the standardized data formats

To map the data items selected by the subject- and organ-specific working groups to international standard vocabularies, we performed a consensus-based mapping procedure, where every concept was mapped to appropriate vocabularies SNOMED CT for general concepts [11], LOINC for observations [7], *International Statistical Classification of Diseases and Related Health Problems, 10th revision, German modification* (ICD-10-GM) for diagnoses [12], *Anatomical Therapeutic Chemical Classification System* (ATC) for Germany for drugs and active ingredients [13], *Unified Code for Units of Measure* (UCUM) for measurement units [14]) by two medical information scientists independently. Ambiguities and non-matching mappings were then discussed within the development team and in close collaboration with the medical experts of the subject- and organ-specific working groups until consensus was achieved. The data item-to-concept mappings were annotated on ART-DECOR, an open-source collaboration platform for creating and maintaining dataset element descriptions [15].

As for the GECCO dataset, the format for data exchange was specified using HL7 FHIR resources. The mapping of data items to FHIR resources was performed in an iterative, consensus-based workflow among the development team. Wherever possible, published FHIR profiles from the GECCO dataset, from the Medical Informatics Initiative (MII) [16] or the National Association of Statutory Health Insurance Physicians (“Kassenärztliche Bundesvereinigung”; KBV) [17] – in this order of priority – served as the base definition for the future extension module profiles.

The profiles and value sets were specified using the FHIR Shorthand (FSH) language (version 1.2.0) and translated to Structure Definition JSON files using the HL7 FSH SUSHI software package (version 2.2.3) [18,19]. We required that at least one exemplary instance be defined for every profile. Syntactic validation of the profiles and value sets definitions was performed using the error-free conversion of the FSH files to JSON using SUSHI and subsequent validation of each profile with their defined instances using the HL7 FHIR validator as implemented in the FHIR Shorthand Validator Python package (version 0.2.2) [20]. After successful syntactic validation of a set of profiles, the profiles were subjected to a two-stage review process as follows. First, the profiles and corresponding value sets and extensions were internally reviewed for semantic appropriateness with the GECCO core developer (JS). After all necessary changes and approval by the internal reviewer, the profiles were subjected to the second review round by an external FHIR development expert. Subsequent to necessary corrections and

approval of the external reviewer, the respective profiles together with their value sets and optionally extensions and code systems were considered finalized and published to the main branch of the git repository.

The whole development process was performed collaboratively on GitHub. Syntactic validation of the profiles was performed by continuous integration/continuous development (CI/CD) workflows implemented as GitHub actions. Semantic validation during the internal and external review rounds was performed using pull requests to two different git branches. After the final approval, profiles and value sets were merged into the main branch of the extension module's repository, which served as the publication branch of the respective module. Since then, maintenance requests and updates of the extension modules are handled via GitHub issues. All kinds of relevant changes become a subject of the internal review as defined above; major changes (e.g., non-technical corrections) are additionally exposed to the external review.

Implementation guides were created for all three extension modules using the FHIR IG publisher tool and a customized template for the implementation guide's HTML pages [21]. The implementation guides are published to GitHub pages and remain automatically synchronized with the main branch of the respective repository via CI/CD workflows.

Results

Dataset definition workflow

We developed an interdisciplinary, iterative, consensus-based workflow for the definition of domain-specific COVID-19 research datasets based on two key requirements: The first key requirement for the content of the datasets was that the content definition (i.e., selection of data elements) was to be performed in full responsibility by a group of medical experts to ensure that the selected data elements are truly those that are required in research of their respective medical specialty. The second key requirement was to produce FAIR (Findable, Accessible, Interoperable, Reusable) digital assets [22]: The dataset definitions shall be represented in FHIR profiles and implementation guides and these shall be registered on open platforms (Findable), they shall be retrievable through open, free, standard protocols (Accessible), they shall use only standard, international medical terminologies such as SNOMED CT and LOINC (Interoperable) and they shall be released with rich usage guides and examples (FHIR implementation guide) and under a permissive license (Reusable).

To fulfill these requirements, the dataset definition workflow consists of four phases: Content definition, mapping, quality assurance and publication (Figure 1). In the content definition phase, a group of medical experts from a particular medical specialty are approached by the development team consisting of medical information specialists and asked to provide a list of the data elements that are most relevant to patient-related COVID-19 research in their respective medical specialty. How the medical expert group compiles the list in detail is left to their discretion (e.g., based on systematic literature review, or Delphi consensus processes). The medical information scientists only review the provided lists for consistency and redundancy and compile the final content definition in agreement with the medical experts group. In the mapping phase, all data elements are then mapped to international terminologies in consultation with the group of medical experts. Based on these a logical model and the mappings of data elements to FHIR resources are established. In the quality assurance phase, the FHIR specifications are syntactically validated using automated software tools and then subjected to a two-staged review process with two individual data interoperability and harmonization experts to validate the specifications semantically, i.e., validate that the data elements defined by the group of medical experts are appropriately mapped to international standards. After any required changes, the logical model and the FHIR implementation guide are published openly accessible to the research community in repositories that fulfill the FAIR criteria as closely as possible, such as ART-DECOR[15] for logical models and GitHub or the FHIR Implementation Guide registry for the implementation guide[23].

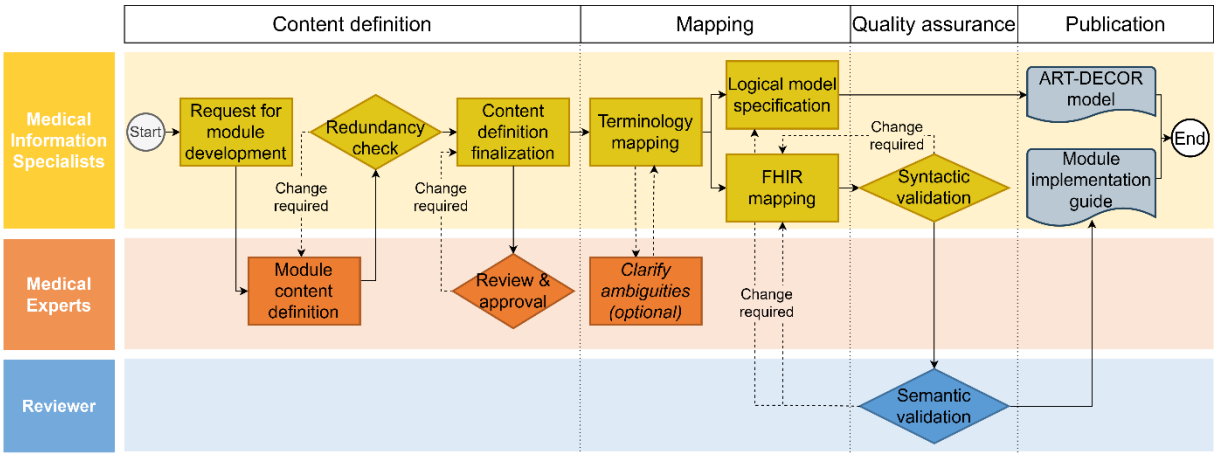

Figure 1 Flowchart of the consensus-based, interdisciplinary dataset definition and mapping workflow for the domain-specific COVID-19 research datasets.

Datasets contents

Groups of medical experts

In the context of the national pandemic cohort net ("Nationales Pandemie Kohorten Netz"; NAPKON) project of the German COVID-19 Research Network of University Medicine [24], so-called subject- and organ-specific working groups were established by the voluntary association of medical experts from different medical specialties. In preparation for the domain-specific dataset definitions that extend the GECCO core dataset, the working groups for *immunology*, *pediatrics,* and *cardiology* were invited by the dataset development group to provide up to 50 data elements with up to 10 response items each that were of particular interest to their field concerning patient-related COVID-19 research and that were not already included in the GECCO core dataset. For the *immunization* dataset definition, physicians from the "NUM-COVIM" study for the determination and use of SARS-CoV-2 immunity [25–27] assumed the role of the organ-specific working group, as no such working group had been established previously.

Overview

The domain-specific dataset definitions developed in this work extend the GECCO core dataset by a total number of 48 data items for the *immunization* extension module, 150 for the *pediatrics* extension module, and 52 for the *cardiology* extension module. These data items have been collected via an iterative consensus-based approach from the respective subject- and organ-specific working groups and belonging to 10 of the 13 data categories of the GECCO dataset (Table 1). Data elements and number of items for each individual extension module are shown in Table 2, Table 3, and Table 4. The full lists of items are shown in the supplementary tables 1, 2, and 3.

GECCO Data Category	GECCO Extension Module		
	Immunization	**Pediatrics**	**Cardiology**
Anamnesis & Risk factors	13	21	6
Complications	24	47	7
Demographics	-	6	-
Epidemiological factors	-	-	-
Imaging	-	2	36
Laboratory values	1	27	2
Medication	1	35	1
Onset of illness & admission	6	2	-
Outcome at discharge	-	-	-
Study enrollment & Inclusion criteria	-	-	-
Symptoms	-	9	-
Therapy	2	1	-
Vital signs	1	-	-
Total items	**48**	**150**	**52**

Table 1 Number of data items per GECCO dataset category for each extension module.

All data items were mapped to the appropriate FHIR resources Observation, Condition, Procedure, MedicationStatement, Encounter, Questionnaire, QuestionnaireResponse, Immunization, ImagingStudy, List, and Specimen, and 26, 14, and 18 profiles (25, 17, and 12 value sets) were created for the *immunization*, *pediatrics*, and *cardiology* extension module, respectively. The data items that were already part of the GECCO dataset and that were not removed during the data selection step were taken over from GECCO and referenced as such in the implementation guides.

The implementation guides for the three extension module have been published on GitHub pages [28–30]. The source FHIR ShortHand (FSH) files have been published on GitHub [31–33]. Logical models and dataset descriptions are hosted on ART-DECOR, an open collaboration platform for modelling dataset definitions and their descriptions and terminology bindings [34–36].

Category	Data Element	FHIR Resource	# items
Anamnesis	Chemotherapy	Procedure	1
	Immunosuppressive therapy	Procedure	1
	Regular Alcohol Intake	Observation	2
COVID-19 infection & treatment	Disease course	Encounter, Procedure	5
	SARS-CoV-2 infection	Condition	1
	SARS-CoV-2 variant	Observation	1
Immunization	Contraindications to immunization	Immunization	2
	Immunizations performed	Immunization	3
	Reason for immunization	Immunization	5
	Willingness to receive additional immunization doses	Observation	1
Immunization reactions	Analgesic or antipyretic drug intake	MedicationStatement	1
	Body temperature	Observation	1
	Complications after immunization	Observation	5
	Medical treatment for adverse reactions	Encounter	3
	Symptoms after Vaccination	Condition	16
Total			**48**

Table 2 Types of data elements in the immunization extension module extending the GECCO core dataset. Shown are the data elements and the FHIR resource they have been mapped to, as well as the number of items for each data element (i.e., different response options).

Category	Data Element	FHIR Resource	# items
Complications	Complications to COVID-19	Condition	47
Demographics	Body measures	Observation	6
Imaging	Echocardiography	Procedure, Imaging Study	1
	PET-CT	Procedure, Imaging Study	1
Immunization	Immunizations performed	Immunization	2
Laboratory values	Laboratory values	Observation	27
Medical history	Chronic Hematologic Diseases	Condition	8
	Chronic Kidney Diseases	Condition	2
	Congenital Disease	Condition	1
	Gastrointestinal Diseases	Condition	6
	Medical History Stem Cells Transplant	Condition	2
Medication	Medication	MedicationStatement, List	35
Symptoms	COVID-19 Symptoms	Condition	9
Therapy	Hospitalization	Observation	2
	Thoracic Drainage	Procedure	1
Total			**150**

Table 3 Types of data elements in the pediatrics extension module extending the GECCO core dataset. Shown are the data elements and the FHIR resource they have been mapped to, as well as the number of items for each data element (i.e., different response options).

Category	Data Element	FHIR Resource	# items
Anamnesis	Chronic cardiologic diseases	Condition	6
COVID-19-related complications	Cardiologic complications of COVID-19	Condition	7
Echocardiography	Echocardiography findings	Observation	20
	Echocardiography procedure	Procedure	3
Electrocardiography	Electrocardiography findings	Observation	11
	Electrocardiography procedure	Procedure	2
Laboratory Values	Laboratory values	Observation	2
Medication	Angiotensin receptor antagonist	MedicationStatement	1
Total			**52**

Table 4 Types of data elements in the cardiology extension module extending the GECCO core dataset. Shown are the data elements and the FHIR resource they have been mapped to, as well as the number of items for each data element (i.e., different response options).

Discussion

We here present an interdisciplinary, iterative, consensus-based workflow to the definition of research datasets, focusing on creating datasets with the most relevant data elements for a particular field of study and on creating universally usable datasets according to the FAIR principles [22]. We applied the workflow to develop three GECCO extension modules that contain data items relevant for COVID-19-related patient research in the *immunization*, *pediatrics*, and *cardiology* fields. These extension modules complement the GECCO core dataset for domain-specified research. The data items are represented in HL7 FHIR profiles and use international terminologies, to ensure a harmonized, standardized, and interoperable dataset definition for these medical domains. The provision of data according to the extension modules introduced in this article will enable cross-institutional and cross-country data collection and collaborative research with a particular focus in *immunization*, *pediatrics*, and *cardiology*.

We have specified and implemented an interdisciplinary, iterative, consensus-based workflow for the selection of data items and the development of the dataset definition. The close collaboration and the constant feedback loops with domain experts from the respective medical specialties right from the beginning of the project, as performed here, are key for the successful development of a useful dataset definition. Indeed, since the selection of relevant data items was driven by the end-users of the dataset, who are the researchers that later will be using the data for their specialized areas of research, the semantic usability of the datasets is guaranteed. Likewise, having medical information specialists develop the formal dataset specification ensures technical interoperability and usability of the dataset definition.

Next to the successful development of dataset definitions, several factors determine a successful deployment or use of the developed extension modules [37]. First and most importantly clear and concise documentation of how to implement and provide data using the dataset definition is required. For FHIR-based dataset definitions, so-called implementation guides are used to provide both a narrative overview as well as technical details on the dataset definition [38]. Thus, we have created and published implementation guides for each of the here-developed extension modules. Second, the example implementations of the extension modules serve as a blueprint for developers and data engineers who implement the extension modules for their clinical databases. From our experience with the implementation of the GECCO dataset, well-defined example data items may be of equal if not higher importance than the technical description of the dataset specification, as developers and engineers tend to use the examples as blueprints for their implementation. Thus, we equipped every FHIR profile defined in the extension modules with at least one example. These examples are incorporated and issued within the implementation guides of the modules. Specifically, we aimed to

provide one example for each different category of response option per profile. Thirdy, the actual implementation of the extension modules should be part of follow-up infrastructure projects to supply funding and resources for filling the dataset definition with actual data. For the GECCO dataset, this is ensured by follow-up projects of the German COVID-19 Research Network of University Medicine ("Netzwerk Universitätsmedizin"), such as CODEX+, which includes several implementation tasks that are actively using the GECCO dataset items [39] and further projects [40–43]. Fourth, once the dataset definitions are implemented and leveraged in use cases, additional demands to the dataset are likely raised or issues with existing definitions are revealed. The maintenance of existing definitions (e.g., performing technical corrections or even evolving the definitions or adding new items) is, therefore, necessary and must be organized and funded. Last, successful use of the extension modules is also highly dependent on the degree of interoperability of the dataset definitions in the first place [1,44,45]. For example, the use of questionnaires to assess certain features is common in clinical research. However, depending on the exact wording of the question and the number and wording of response options, results from different studies might not be directly comparable although they assessed the same features, as the questions and response options differ between studies. In the presented extension modules, several items were at first specified in a questionnaire-like fashion and direct implementation of these as Questionnaire resources in FHIR would have limited the applicability of such data elements, especially when aiming to map these elements from an electronic health records (EHR) system. In these cases, we revised the data elements specification to use interoperable concepts rather than questions. Here, repeated consultation with and final approval of the group of medical experts was key to be able to convert questions into interoperable concepts that convey the same information as intended by the content definition of the group of medical experts. In general, we recommend not to use Questionnaire/QuestionnaireResponse FHIR profiles in cases where the information to be represented can be modeled using more general, interoperable concepts and FHIR resources.

Conclusion

We here introduce the development workflow and the resulting dataset definitions for GECCO extension modules for the *immunization*, *pediatrics*, and *cardiology* domains. We have defined and implemented a workflow in which interdisciplinary teams of medical domain experts, medical information scientists and FHIR developers closely collaborate in an iterative, consensus-based fashion for the successful development of useful and interoperable dataset definitions. This workflow may serve as a blueprint for further dataset definition projects, such as further dataset definitions for extending the GECCO core dataset. The extension modules described in this work have been validated and published. Their implementation and active use are anticipated in the context of current nationwide COVID-19 research networks in Germany.

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Conflict of interests

The authors declare that they have no competing interests.

Data Availability

The implementation guides for the three extension modules have been published on GitHub pages [28–30]. The source FHIR ShortHand (FSH) files have been published on GitHub [31–33]. Dataset descriptions can be found on ART-DECOR [34–36]

Authors' contributions

All authors contributed to the development of the extension modules. GL, TH, SB, LR, JS, AB, ST performed terminology mapping, FHIR profiling and critical review of the concept and resource mappings. TH, SB, LR defined the datasets in ART-DECOR. DH, FK, LES, FB, FE, NT, RB, AF, MD developed and compiled the list of data items for the datasets. SR, LL and MU coordinated the project and the consensus finding process within and between working groups. JJV, CvK, ST conceived the work. GL drafted the manuscript. All authors read and approved the final manuscript.

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Supplementary Appendix

The following tables show the data items that are included in the immunization extension module (Table S 1), the pediatrics extension module (Table S 2), and the cardiology extension module (Table S 3). Note that these tables list only the data items of the extension modules that are not included in the GECCO core dataset and that the complete dataset definition for each specialty consists of the GECCO core dataset together with the data items of the extension module.

GECCO Immunization extension module

Category	Data Element	FHIR Resource	Item
Anamnesis	Chemotherapy	Procedure	Chemotherapy
	Immunosuppressive therapy	Procedure	Immunosuppressive therapy
	Regular Alcohol Intake	Observation	Frequency
			Quantity
COVID-19 infection & treatment	Disease course	Encounter, Procedure	No symptoms
			Treated at home
			Treated at hospital with oxygen therapy
			Treated at hospital without oxygen therapy
			Treated at intensive care unit
	SARS-CoV-2 infection	Condition	SARS-CoV-2 infection
	SARS-CoV-2 variant	Observation	SARS-CoV-2 variant
Immunization	Contraindications to immunization	Immunization	Allergy
			Pregnancy
	Immunizations performed	Immunization	Date
			Lot number
			Type
	Reason for immunization	Immunization	Everybody gets vaccinated
			Protection of private environment from infection/disease
			Protection of themself from infection/disease
			Protection of work environment from infection/disease
			Worrying about disadvantages
	Willingness to receive additional immunization doses	Observation	Willingness to receive additional immunization doses
Immunization reactions	Analgesic or antipyretic drug intake	MedicationStatement	Analgesic or antipyretic drug intake
	Body temperature	Observation	Body temperature after vaccination
	Complications after immunization	Observation	Allergic reaction after immunization
			Injection site erythema
			Injection site pain at rest
			Injection site pain during pressure/movement
			Injection site swelling
	Medical treatment for adverse reactions	Encounter	Ambulatory
			Inpatient
			No treatment
	Symptoms after Vaccination	Condition	Chill

			Diarrhea
			Difficulty breathing
			Dyspnea
			Exhaustion
			Fatigue
			Feeling feverish
			Fever
			Fever with chills
			Joint pain
			Liquid stool
			Loose stool
			Muscle pain
			Nausea
			Soft stool
			Vomiting symptom

Table S 1 Data items in the immunization extension module extending the GECCO core dataset. Shown are the data elements and the FHIR resource they have been mapped to, as well as the items for each data element (i.e., different response options).

GECCO Pediatrics extension module

Category	Data Element	FHIR Resource	Item
Complications	Complications to COVID-19	Condition	Anemia
			Arterial aneurysm
			Ascites
			Aspergillosis
			Bacterial arthritis
			Bacterial endocarditis
			Bacterial meningitis
			Bacterial osteomyelitis
			Bronchiolitis
			Bronchitis
			Chlamydial infection
			Chronic fatigue syndrome
			Colitis
			Disease caused by Adenovirus
			Disease caused by Coronaviridae
			Disease caused by Human bocavirus
			Disease caused by Rhinovirus
			Disorder of liver
			Haemophilus influenzae infection
			Human metapneumovirus infection
			Ileitis

			Infection caused by Candida albicans
			Infection caused by Escherichia coli
			Infection caused by Klebsiella
			Infection caused by Pseudomonas aeruginosa
			Infection caused by Staphylococcus aureus
			Infection caused by Streptococcus viridans group
			Infection caused by enterococcus
			Infection of bloodstream
			Influenza
			Invasive Group A beta-hemolytic streptococcal disease
			Invasive Streptococcus pneumoniae disease
			Legionella infection
			Meningococcal infectious disease
			Mycoplasma infection
			Organic mental disorder
			Parainfluenza
			Peritonitis
			Pertussis
			Post-acute COVID-19
			Procedure needed Where Associated procedure = Resuscitation
			Pyelonephritis
			Respiratory syncytial virus infection
			Seizure disorder
			Streptococcus agalactiae infection
			Streptococcus pyogenes infection
			Syncope
Demographics	Body measures	Observation	Birth height
			Birth height (percentile)
			Body mass index
			Body mass index (percentile)
			Head circumference
			Head circumference (percentile)
Imaging	Echocardiography	Procedure, Imaging Study	Echocardiography
	PET-CT	Procedure, Imaging Study	Positron emission tomography with computed tomography
Immunization	Immunizations performed	Immunization	Viral vector vaccine
			mRNA vaccine
Laboratory values	Laboratory values	Observation	Alanine Aminotransferase
			Albumin
			Amylase
			Calprotectin
			Cells in CSF
			Complement C3
			Complement C4
			Creatine kinase
			Creatine kinase.MB

			Erythrocyte sedimentation rate
			Glucose in CSF
			Hematocrit
			IgG
			Interleukin 10
			Interleukin 2 Receptor Soluble
			Lactate in CSF
			Lipase
			Natural killer cell function
			Neutrophil cytoplasmic Ab
			Nuclear Ab
			Protein in CSF
			Prothrombin time (PT)
			SARS-CoV-2 RT in stool
			SARS-CoV-2 RT in urine
			Sodium
			Triglyceride
			Urea
Medical history	Chronic Hematologic Diseases	Condition	Blood coagulation disorder
			Glucose-6-phosphate dehydrogenase deficiency anemia
			Hemolytic anemia
			Iron deficiency anemia
			Myelodysplastic syndrome
			Neutropenic disorder where Clinical course = Chronic
			Sickle cell-hemoglobin SS disease
			Thalassemia
	Chronic Kidney Diseases	Condition	Disorder of the urinary system where Occurrence = Congenital
			Kidney disease where Occurrence = Congenital
	Congenital Disease	Condition	Congenital Disease
	Gastrointestinal Diseases	Condition	Allergy to cow's milk protein
			Celiac disease
			Chronic constipation
			Disorder of bile duct
			Disorder of gastrointestinal tract
			Inflammatory bowel disease
	Medical History Stem Cells Transplant	Condition	History of bone marrow transplant
			History of peripheral stem cell transplant
Medication	Medication	MedicationStatement	Blood product
			Bronchodilator
			Inotropic agent
			Medicinal product acting as antibacterial agent
			Medicinal product acting as hemostatic
			Product containing anakinra
			Product containing aspirin
			Product containing human immunoglobulin
			Product containing nitric oxide

			Product containing tocilizumab
			Vasopressor
		MedicationStatement, List	Alkylating agent
			Anti-CD20 antibody
			Anti-CD3 antibody
			Anti-CD3/CD19 antibody
			Anti-CD52 antibody
			Antimetabolite
			B cell activating factor inhibitor
			Calcineurin inhibitor
			Cytotoxic T-lymphocyte-associated protein 4 inhibitor
			Equine antithymocyte immunoglobulin
			Immunoglobulin E
			Integrin inhibitor
			Interferon
			Interleukin 1 receptor antagonist
			Interleukin 17 receptor antagonist
			Interleukin 2 receptor antagonist
			Interleukin 6 receptor antagonist
			Janus kinase inhibitor
			Mammalian target of rapamycin-Kinase inhibitor
			Protein-tyrosine kinase inhibitor
			Sphingosine analogue
			Steroid
			Tumor necrosis factor alpha inhibitor
			interleukin 23 receptor antagonist
Symptoms	COVID-19 Symptoms	Condition	Delirium
			Eruption of skin
			Large liver
			Myoclonus
			Pain in throat
			Palmar erythema
			Raspberry tongue
			Splenomegaly
			Swallowing painful
Therapy	Hospitalization	Observation	Intensive care treatment duration
			Total length of stay
	Thoracic Drainage	Procedure	Thoracic Drainage

Table S 2 Data items in the pediatrics extension module extending the GECCO core dataset. Shown are the data elements and the FHIR resource they have been mapped to, as well as the items for each data element (i.e., different response options).

555 ## GECCO Cardiology extension module

Category	Data Element	FHIR Resource	Item
Anamnesis	Chronic cardiologic diseases	Condition	Atrial fibrillation
			Atrial flutter
			Cardiomyopathy
			Congenital heart disease
			Heart failure
			History of coronary artery bypass grafting
COVID-19-related complications	Cardiologic complications of COVID-19	Condition	Bacterial respiratory infection
			Cardiogenic shock
			Complete atrioventricular block
			Myocarditis
			Pericardial effusion
			Ventricular fibrillation
			Viral disease
Echocardiography	Echocardiography findings	Observation	Abscess of heart
			Aortic valve regurgitation
			Aortic valve stenosis
			Heart valve disorder
			Left Ventricular Ejection Fraction
			Left ventricular hypertrophy
			Left ventricular wall motion abnormality
			Mitral valve regurgitation
			Mitral valve stenosis
			Paradoxical cardiac wall motion
			Pericardial effusion
			Pulmonic valve regurgitation
			Pulmonic valve stenosis
			Right ventricular hypertrophy
			Thrombosis
			Tricuspid annular plane systolic excursion (TAPSE)
			Tricuspid valve regurgitation
			Tricuspid valve stenosis
			Vegetation of heart
			Ventricular hypertrophy
	Echocardiography procedure	Procedure	Date
			Echocardiography
			Type of echocardiography
Electrocardiography	Electrocardiography findings	Observation	Atrial ectopics
			Atrioventricular Block
			Bundle Branch Block
			Inverted T wave
			Low QRS voltages
			Premature ventricular contractions
			QRS Axis

			QRS Interval
			QT Interval
			ST Interval
			Sinus rhythm
	Electrocardiography procedure	Procedure	12 lead electrocardiogram
			Date
Laboratory Values	Laboratory values	Observation	Troponin I
			Troponin T
Medication	Angiotensin receptor antagonist	MedicationStatement	Angiotensin Receptor Antagonist

Table S 3 Data items in the cardiology extension module extending the GECCO core dataset. Shown are the data elements and the FHIR resource they have been mapped to, as well as the items for each data element (i.e., different response options).