



Interoperable Data Export by GAIA for Digital Health Applications

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16.06.2021	1.0	Initial release

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1. Introduction

This document aims to describe the interoperable data export format used by GAIA AG for its products that are recognized as “Digital Health Applications” (digitale Gesundheitsanwendungen, DiGA) pursuant to German Digital Healthcare Act (Digitale-Versorgung-Gesetz, DVG). GAIA AG is a research-based public health company that develops innovative digital therapy solutions and medical devices, which are classified software as a medical device (SaMD).

1.1. Communication & Inquiries

- info@gaia-group.com

1.2. Background

Digital health applications are subject to various requirements and German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) publishes a guide for manufacturers, service providers and users of such applications to clarify these. According to the DiGA guide published by BfArM, a DiGA shall allow the insured person to export their data collected from the DiGA in two distinct formats for two distinct purposes. One as a human-readable, printable format to allow the user to use it for their own purposes and to share with their physician. The other as a machine-readable, interoperable format that can be processed by other digital applications [1].

For interoperability, an open, internationally recognized standard is recommended until relevant medical information objects (MIOs) are defined by the Federal Association for Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV), which in the future will be exchangeable via the electronic patient record (elektronische Patientenakte, ePA).

1.3. Scope and Disclaimer

This document details the content of the interoperable data export that is made available in GAIA’s DiGA products. Currently, GAIA products *velibra*, *elevida*, *deprexis* and *vorvida* are listed in the DiGA directory. The data export format explained here follows the same basic principles and applies to all present and future DiGA products developed by GAIA.

For interoperable export, GAIA relies on the FHIR® standard published by HL7® [2]. GAIA follows the openly published FHIR® Specification v4.0.1: R4 without further profiling and generates a valid json file as export. The JavaScript Object Notation (JSON) is a standardized, open, text-based format for displaying structured data. This document does not constitute an implementation guide for FHIR®.

HL7®, FHIR® and the FHIR [FLAME DESIGN]® are the registered trademarks of Health Level Seven International and their use does not constitute endorsement by HL7.

1.4. Target Audience

This documented is aimed at various stakeholders (regulators, manufacturers, physicians and patients) in the public health sector.

2. Exporting Data

In the settings page of each product, patients are given the option to export relevant data as a single json file. For this purpose, the FHIR® Bundle resource is used [3]. Bundle resource is a special resource that is used to bring together a self-contained collection of other resources.

Each bundle starts with a data entry structured according to the FHIR® Patient resource, which features information on the data subject [4]. Patients are identified by a unique 12-digit alphanumeric access code that is generated by the system. This resource also contains information on the nickname, the email address and other optional variables the patient has provided during their registration.

Further information regarding the data subject is reported in entries that follow the FHIR® Observation resource [5]. This resource is used to report clinically relevant findings. Entries in this resource can be categorized as “survey” based on HL7’s observation category code system. The entries represented as observations differ based on the content of the product. Following the recommendations of the FHIR® standard, each entry is coded using Logical Observation Identifiers Names and Codes (LOINC) [6]. Where a unique LOINC code is not available for a given survey, the generic LOINC code for patient reported outcomes is used and a text description of the survey is provided for context. Furthermore, details regarding the interpretation are similarly provided with appropriate LOINC codes and text descriptions.

2.1. Resources Used

Resource	Type	Cardinality	Description
Bundle	collection	1..1	A bundle is a unique resource that can be used to store a collection of other resources.
Patient	subject	1..1	Base resource that is used to store patient’s contact data such as self-reported username and email address.
Observation	survey	0..*	Entries consisting of patient reported outcomes with scores calculated by the system based on responses to regular surveys conducted by the program.

2.2. Sample Export

Below is a sample export generated by the product *deprexis*:

```
{
  "resourceType": "Bundle",
  "identifier": {
    "use": "official",
    "value": "DIGA",
    "period": {
      "start": "2021-06-16T13:56:28.632789Z"
    }
  },
  "type": "collection",
```

```

"timestamp": "2021-06-16T13:56:28.632944Z",
"entry": [
  {
    "fullUrl": "27TN1TFHXDXH",
    "resource": {
      "resourceType": "Patient",
      "identifier": [
        {
          "use": "usual",
          "value": "27TN1TFHXDXH",
          "period": {
            "start": "2021-06-16T07:42:26.000000Z"
          }
        }
      ],
      "id": "27TN1TFHXDXH",
      "name": [
        {
          "use": "nickname",
          "text": "Frau Musterfrau"
        }
      ],
      "telecom": [
        {
          "system": "email",
          "value": "musterfrau@example.com"
        }
      ],
      "gender": "female",
      "birthDate": "1998"
    }
  },
  {
    "fullUrl": "5c564f8edb160a3ee84f081a08852fc0c1277e631963d0f5505afc7a2c6970f4",
    "resource": {
      "resourceType": "Observation",
      "id": "5c564f8edb160a3ee84f081a08852fc0c1277e631963d0f5505afc7a2c6970f4",
      "status": "final",
      "category": [
        {
          "coding": [
            {
              "system": "http://terminology.hl7.org/CodeSystem/observation-category",
              "code": "survey",
              "display": "Survey"
            }
          ]
        }
      ],
      "code": {
        "coding": [

```

```

    {
      "system": "http://loinc.org",
      "code": "44249-1",
      "display": "PHQ-9 quick depression assessment panel [Reported.PHQ]"
    }
  ],
  "text": "PHQ-9 quick depression assessment panel"
},
"subject": {
  "reference": "Patient/27TN1TFHXDXH",
  "display": "Frau Musterfrau"
},
"effectiveDateTime": "2021-06-16T07:46:37.000000Z",
"valueInteger": 12,
"interpretation": [
  {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "LL382-3",
        "display": "PHQ-9 Interp-score"
      }
    ]
  },
  "text": "Scores range between 0-27, where higher values represent stronger depressive symptoms."
}
]
}
},
{
  "fullUrl": "54444536892dca56879a81ceb48e3b6cdb6cde05cdd7e529738f6978c4834243",
  "resource": {
    "resourceType": "Observation",
    "id": "54444536892dca56879a81ceb48e3b6cdb6cde05cdd7e529738f6978c4834243",
    "status": "final",
    "category": [
      {
        "coding": [
          {
            "system": "http://terminology.hl7.org/CodeSystem/observation-category",
            "code": "survey",
            "display": "Survey"
          }
        ]
      }
    ]
  }
},
"code": {
  "coding": [
    {
      "system": "http://loinc.org",
      "code": "89196-0",

```

```
    "display": "Patient reported outcome measure panel"
  }
],
"text": "A daily mood check survey with 6 items developed by GAIA."
},
"subject": {
  "reference": "Patient/27TN1TFHXDXH",
  "display": "Frau Musterfrau"
},
"effectiveDateTime": "2021-06-16T07:47:14.000000Z",
"valueInteger": 13,
"interpretation": [
  {
    "coding": [
      {
        "system": "http://loinc.org",
        "code": "89193-7",
        "display": "Patient reported outcome measure score interpretation"
      }
    ],
    "text": "Scores range between 0-24, where higher values represent a better mood."
  }
]
}
]
}
]
}
```

3. References

- [1] Federal Institute for Drugs and Medical Devices. *The Fast-Track process for Digital Health Applications (DiGA) according to Section 139e SGB V: A guide for Manufacturers, Service Providers, and Users*. August 2020. (Accessed on 07.06.2021)
https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.pdf?__blob=publicationFile&v=2.
- [2] HL7® FHIR® Release 4. November 2019. (Accessed on 16.06.2021) <https://www.hl7.org/fhir/>.
- [3] HL7® FHIR® Bundle Resource. November 2019. (Accessed on 16.06.2021)
<http://hl7.org/fhir/bundle.html>.
- [4] HL7® FHIR® Patient Resource. November 2019. (Accessed on 16.06.2021)
<http://hl7.org/fhir/patient.html>.
- [5] HL7® FHIR® Observation Resource. November 2019. (Accessed on 16.06.2021)
<http://hl7.org/fhir/observation.html>.
- [6] Logical Observation Identifiers Names and Codes. June 2021. (Accessed on 16.06.2021)
<https://loinc.org/>.