FAIR Connect article

Connecting Health Data across jurisdictions through FAIR Data-visiting: Ownership, Localisation and Regulatory compliance (OLR)

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Keywords: Health Data, Ownership, Localisation, Data Regulation, VODAN-Africa

Date: Oct 9, 2022

Utilising the Guidelines of Findable, Accessible, Interoperable and Re-usable (FAIR)-Data[1], the Virus Outbreak Data Network (VODAN)-Africa investigates how the quality of health-data available for, and from, Africa can be enhanced. The research responds to the concern about the current practices of health data being moved out of jurisdictions, without control by the data subject over the continued life-cycle of the data. In order to remain compliant with the European Union (EU) General Data Protection Regulation (GDPR, 2016)[2], which came into force in 2018, and following the FAIR-Data guidelines, investigation of the possibility of curating federated, interoperable and reusable health data is relevant. The GDPR assigns ultimate data-control to the data subject to whom the data refers, and finds that in collaboration with any EU data processor, handling must be GDPR compliant. To adhere to GDPR standards, it is necessary that data pertaining to a data subject remain within the jurisdiction where such data is produced. Increasingly, the data ownership is subject to GDPR-equivalent regulatory principles in non-EU geographies, including in Africa[3].

The research conducted includes the development of an architecture in nine African countries, with a deployment of a minimum viable product (MVP) in 88 health facilities in a natural setting[4]. VODAN-Africa achieved a data-visiting, multi-use architecture in which data is entered once, allowing for horizontal interoperability

[1] Wilkinson, M., Dumontier, M., Aalbersberg, I. J., Appleton, G., Axton, M., Baak, A., et al.: The FAIR Guiding Principles for scientific data management and stewardship. Scientific Data 3(1), 1–9 (2016). https://doi.org/10.1038/sdata.2016.1

[2] EU. 2016. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) OJ L 119, 4.5.2016, p. 1–88

[3] Van Reisen, M., Oladipo, F., Mpezamihigo, M., Plug, R., Basajja, M., Aktau, A., Purnama Jati, P.H., Nalugala, R., Folorunso, S., Amare, Y.S., Abdulahi, I., Afolabi, O.O., Mwesigwa, E., Taye, G.T., Kawu, A., Ghardallou, M., Liang, Y., Osigwe, O., Medhanyie, A.A., Mawere, M.: Incomplete COVID-19 data: The curation of medical health data by the Virus Outbreak Data Network-Africa. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00166

[4]VODAN-Africa. Website/ Online: https://vodan-totafrica.info/vodan-news-page.php?i=48&a=vodan-africa-to-deploy-digital-health-systems-across-africa - accessed Oct 10, 2022

(within the community) and vertical interoperability (with other platforms)[5]. The investigation concluded that key aspects requiring attention for interoperability in FAIR-compliant architectures are: Data Ownership, Localisation and Regulatory compliance in jurisdiction (OLR).

Ownership

Ownership is a critical principle from which access and control arrangements are derived[3,6]. In VODAN-Africa the data is stored in residence, governed by data use agreements, and compliant with the regulations identified in each locality[4]. In multiple jurisdictions, data-ownership is federated, and requires data-localisation. The precise definition of data-ownership may differ in the different regulatory frameworks in place for different situations. The ultimate ownership of the personal data of the health data resides with the data subject, but when the data is aggregated into statistical data elements ownership can be transferred. The principle that personal data pertains to the data subject is adhered to as a basic non-negotiable principle in VODAN-Africa.

Localisation

Data Localisation is necessary if the standard of data Ownership is to be met. VODAN-A tested the possibility of repositing data in each of the participating health clinics. The data is entered only once and stored in AllegroGraph, from where it is available for statistical analysis in the local data dashboard. In addition, horizontal interoperability is arranged across health facilities in the community[5]. The VODAN-A dashboard serves to visualise health population trends. Vertical interoperability with other platforms is supported through interoperability schemas[5]. Specific functions, such as an automated computation and HMIS reporting into DHIS2 are arranged within the architecture deployed in residence.

The VODAN-A research found that a 'locale' for data localisation can differ across different geographies. In some locations, depending on availability of resources, a

[5] Amare,S.Y, Taye, G.T, Gebreselassie, T.G, Van Reisen, M.,: Realising health data-interoperability in low connectivity settings: the case of VODAN-Africa. FAIR Connect (Forthcoming)

[6] Jati PH, van Reisen M, Flikkenschild E, Oladipo F, Meerman B, Plug R, Nodehi S. Data access, control, and privacy protection in the VODAN-Africa architecture. Data Intelligence. 2021:1-29.

client-server deployment architecture was followed. In a client-server set-up, the MVP is deployed in a local setting and the issue of ownership is adhered to, through the data ownership structure in the client-server set-up. In other locations, the data resides within the health facility proper. In all cases, the personal health data did not leave the jurisdiction.

Regulatory compliance in the jurisdiction

Through a federated data-visiting set up, VODAN-A achieved compliance with data according to the regulatory framework in place in each jurisdiction[6]. Due to the sensitive nature of personal health data, full attention must be given to the rights and obligations under the regulatory frameworks in each jurisdiction in which the data is produced, in combination with the obligation to assign rights to the data subject, as part of the founding principles of VODAN-A.

Ownership, Localisation and Regulatory compliance: OLR

It is proposed that the acronym FAIR-OLR be used to refer to the set of basic qualities of a health information architecture that allows Ownership, Localisation and Regulatory Compliance (OLR) of the data in the respective jurisdictions. This includes respect for the Health Information System in place.

FAIR-OLR refers to data that is federated, connected to the data subject, and under the responsibility of the data authority and processors where data is produced and reposited. The FAIR-OLR set of principles allows for data interoperability and reuse across borders in different jurisdictions and modes of operations, taking full advantage of the available semantic descriptions of the data, as well as its contextual qualities. FAIR-OLR advances the ethical and legal principles of personal data protection[7]. FAIR-OLR mitigates against health data being (systematically) removed from the African continent, and contributes to building health infrastructures that generate value from data for better health outcomes.

[7] EU. 2016. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) OJ L 119, 4.5.2016, p. 1–88

FAIR-OLR governance framework

FAIR-OLR provides a governance framework for FAIR tools and FAIR enabling tools, which are themselves FAIR. FAIR principles have clearly outlined how to make data FAIR. The Go-train, Go-build and Go-change modalities of Go-FAIR set a foundation for focusing on how to create awareness, and build tools to move FAIR implementation forward[8]. The authors identified the gap in the governance of FAIR implementation during the design of vertical and horizontal interoperability across jurisdictions.

The governance has local and global dimensions and identifies how local governance frameworks interplay with global frameworks. VODAN-Africa data production and use includes data processing agreements which relate to GDPR in terms of the principles, process, and standards that a given local implementation follows, and the adherence of these with policy directions in the jurisdictions at hand[9]. In addition to the advantages of data being curated with FAIR-OLR guidelines, the tooling also needs to follow these guidelines. Global FAIR enabling tools need to be governed, as at some point the tools may evolve from being open source to closed source, or from being FAIR to otherwise, or may change standards without prior notice to the FAIR enabling resource using the tools. Looking at

[8] Van Reisen, M., Stokmans, M., Basajja, M., Ong'ayo, A. O., Kirkpatrick, C., Mons, B.: Towards the tipping point of FAIR implementation. Data Intelligence 2(2020), 264–275. doi: 10.1162/dint_a_00049

[9] Basajja, M., Van Reisen, M., Oladipo, F.: FAIR Equivalency with regulatory framework for digital health in Uganda. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00170; Purnama Jati, P.H.: FAIR Equivalency in Indonesia's digital health framework. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00171; Taye, G.T., Amare, Y.S., Gebremeskel, G.T., Medhanyie, A.A., Ayele, W., Habtamu, T., Van Reisen, M.: FAIR Equivalency with regulatory framework for digital health in Ethiopia. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00172; Chindoza, K.: Regulatory framework for eHealth data policies in Zimbabwe: Measuring FAIR Equivalency. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00173; Kawu, A.A., Joseph, E., Abdullahi, I., Maipanuku, J.Y., Folorunso, S., Basajja, M., Oladipo, F., Ibrahim, H.L.: FAIR Guidelines and data regulatory framework for digital health in Nigeria. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00174; Thea, E.I., Nalugala, R., Nandwa, W., Obwanda, F., Wachira, A. Cartaxo, A.M.: FAIR Equivalency, regulatory framework and adoption potential of FAIR Guidelines in health in Kenya. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00175

ontology services provided by BioPortal, lots of variants emerge (i.e. AgroPortal, VodanPortal); with growth in demand for the services and in the number of requests, such tools will develop.

During localisation there is a trade-off that needs to be made. Deploying globally available tools locally requires data stewardships skills and the availability of resources. There is a need to make what is locally available to be globally findable and accessible. There is also a need for tooling to be deployed, owned and governed locally in a federated manner. This helps to ensure sustainability, avoid downtime, reduce the cost of connectivity and other resource utilisation, and enhance performance. This fosters reuse of existing and emerging FAIR enabling tools.

The FAIR-OLR defines principles and specifications on how to handle the behaviour that arises as a result of the interaction of FAIR tools with other FAIR tools and with FAIR enabling tools. Ways of handling involve issues such as performance, trust, security, logging of transaction, mediation and orchestration of interoperability.

Table 1: FAIR-OLR Principles

FAIR	Ownership (L,G,B)	Localisation	Regulatory compliance
Findable	Owned locally and findable globally	Locally deployable and globally findable	According to the regulatory frameworks in place in each jurisdiction and aligned with globally defined regulatory frameworks.
Accessible	Defined and allowed locally to be accessed globally	Locally deployable and globally accessible	
Interoperable	Knowledge and ontologies defined with local ownership	Knowledge and ontologies defined locally and stored globally and with copies stored locally	
Reusable	Re-usable while ownership is protected	Local storage for global and local re-use	

An African Health Data Space

FAIR-OLR is an iteration of the WHO proposition of SMART[10] health data. Building on the idea that the future of health is in the interoperability of digital health data, it is critical to reflect on the nature of a Health Data Space in which this interoperability is shaped, as well as the qualities of the data that will populate it. The advantage of

[10] Mehl G, Tunçalp Ö, Ratanaprayul N, Tamrat T, Barreix M, Lowrance D, Bartolomeos K, Say L, Kostanjsek N, Jakob R, Grove J. WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age. The Lancet Digital Health. 2021 Apr 1;3(4):e213-6.

an African Health Data Space is maximised if based on an inclusive, ethical FAIR data pipeline, which is Federated AI-ready and that respects the ownership of health data by the data subject; the localisation of data to where such data is produced; and compliance with the regulatory frameworks in place.

Conclusions

Data-visiting in federated data architectures enhances the possibilities of promoting the ownership of data (by the data subject), the localisation of data production, and the regulatory compliance of data handling within the regulatory frameworks relevant in each jurisdiction. This is referred to as FAIR-OLR and helps build the trust of a federated, ethical data pipeline that produces quality data for machine-learning and AI purposes, for horizontal (within community) and vertical (between community) use. The FAIR-OLR is a WHO Smart iteration that will help set the guidelines for a Health Data Space and, importantly, an African Health Data Space. This notion recognises that the value of health data from Africa belongs in Africa and must be used for the enhancement of quality health within the African continent.

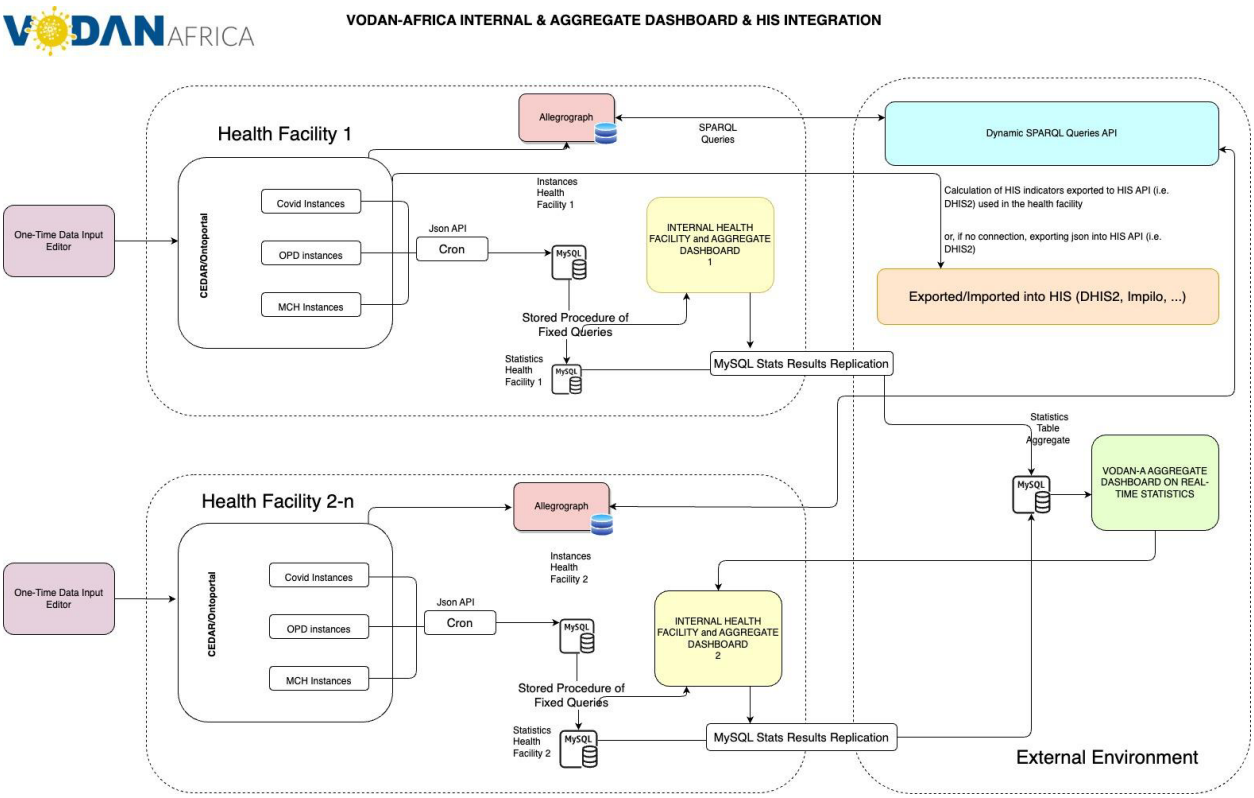

Figure 1: Van Reisen, M., Oladipo, F., Mpezamihigo, M., Plug, R., Basajja, M., Aktau, A., Purnama Jati, P.H., Nalugala, R., Folorunso, S., Amare, Y.S., Abdulahi, I., Afolabi, O.O., Mwesigwa, E., Taye, G.T., Kawu, A., Ghardallou, M., Liang, Y., Osigwe, O., Medhanyie, A.A., Mawere, M.: Incomplete COVID-19 data: The curation of medical health data by the Virus Outbreak Data Network-Africa. Data Intelligence 4(4) (2022). doi: 10.1162/dint_a_00166

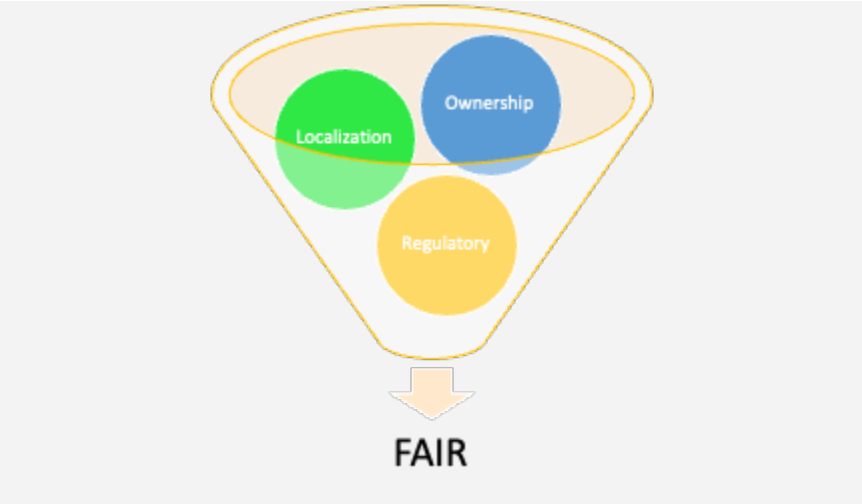

Figure 2: OLR feeds into FAIR-Guidelines

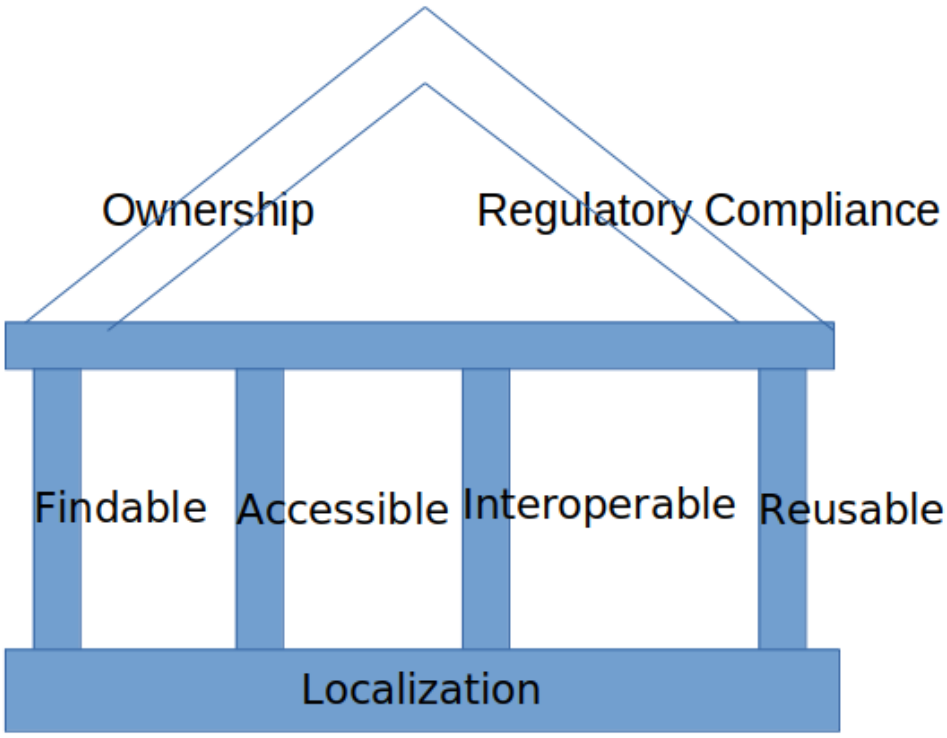

Figure 3: The FAIR-house completed with the foundation of localization (federated data) and delivering a rooftop for data ownership and regulatory compliance of data handling.