### Rationale

The purpose of this page is to present an application scenario illustrating the need for FAIR FHIR resources and demonstrating the benefits of their existence to the field of medical research studies.

### Background

Clinical and epidemiological research has a wealth of health-related data from both cohort studies and surveillance programs (healthy individuals) and clinical trials and registries (patients), which feature deep phenotyping of study participants using interventional therapies, medical observations, surveys, or molecular genetic profiles. These prospective data collections are typically of high quality. Their analyses lead to the development and validation of therapeutic, as well as preventive and quality assurance measures for single individuals or specific populations.

### What is the problem and why does it need to be addressed in HL7 FHIR?

Data from medical research studies continue to be shared on a limited basis, even though this would have potential benefits for science and society. Reasons for this include fear of loss of intellectual property or regulatory concerns, but also technical barriers to research publication, data collection instruments, and the underlying datasets themselves. In practice, many of the data are not sufficiently standardized, which makes both their publication and their interpretation or reproducibility difficult. A variety of existing approaches has led to the current lack of a de facto standard.

### What should be achieved?

FHIR provides a sophisticated information model together with a modern technological framework. Although development is currently ongoing, the broad applicability and widespread support in the community is evident. FAIR Data principles aim to make better use of existing digital assets. Although medical research studies are accompanied by a large number of regulated documents and data, these are generally neither findable nor accessible. They rarely follow coordinated interoperable specifications, which affects reproducibility and reusability.

### What steps are needed to achieve the goals?

#### Support for Findability

* Interventional clinical trials are often registered in national or international registries.
  + entries are often not current.
  + observational trials and epidemiological studies are rarely registered
* There is a WHO Core Data Set, but it is not really machine-readable.
  + lots of text fields
  + unclear description what to describe in certain fields
* Example: <title>
  + primary title and/or secondary tilte
  + short title and/or long title
  + scientific title and/or public title
  + title in English and/or other languages
* Goal: Improve findability by mapping existing attributes from WHO Core Data Set and other standard bodies to FHIR ResearchStudy and other artifacts

#### Support for Accessibility

* Rather than doing a search by text strings, we should improve accessibility with regards to providing some kind of specification how registries should "offer" data
  + It's intended like FHIR Terminology providing basic operations

#### Support for Interoperability

* Many of the attributes in FHIR ResearchStudy are not broadly supported by use in the community.
* Generic attributes such as category, type or class can be used in a misleading way

#### Support for Reusability