This paper presents an ontological base for the semantic framework for reporting, coordinating and searching data on the European and international rare diseases research registries. There are 24 European Reference Networks (ERNs) with numerous healthcare providers across Europe reporting on complex or rare diseases (RD) and conditions that require highly specialised treatment, and concentrated knowledge and resources through 32 registries. The registries use concepts from different vocabularies and metadata, leading to poor data interoperability at the syntactic and semantic level. The semantic model helps to overcome fragmentation and improve the effective use of data about rare disease patient and biosample registries, to facilitate scientific research progress and decrease unnecessary hardship and prolonged suffering of rare diseases patients via data sharing and coordination across registries in the RD care centres in European Reference Networks (ERNs).

Background: The Zebrafish Anatomy Ontology (ZFA) is an OBO Foundry ontology that is used in conjunction with

the Zebrafish Stage Ontology (ZFS) to describe the gross and cellular anatomy and development of the zebrafish,

Danio rerio, from single cell zygote to adult. The zebrafish model organism database (ZFIN) uses the ZFA and ZFS to

annotate phenotype and gene expression data from the primary literature and from contributed data sets.

Results: The ZFA models anatomy and development with a subclass hierarchy, a partonomy, and a developmental

hierarchy and with relationships to the ZFS that define the stages during which each anatomical entity exists. The

ZFA and ZFS are developed utilizing OBO Foundry principles to ensure orthogonality, accessibility, and

interoperability. The ZFA has 2860 classes representing a diversity of anatomical structures from different anatomical

systems and from different stages of development.

Conclusions: The ZFA describes zebrafish anatomy and development semantically for the purposes of annotating

gene expression and anatomical phenotypes. The ontology and the data have been used by other resources to

perform cross-species queries of gene expression and phenotype data, providing insights into genetic relationships,

morphological evolution, and models of human disease.

Background: Recently, exchanging data and information has become a significant challenge in medicine. Such

data include abnormal states. Establishing a unified representation framework of abnormal states can be a difficult

task because of the diverse and heterogeneous nature of these states. Furthermore, in the definition of diseases

found in several textbooks or dictionaries, abnormal states are not directly associated with the corresponding

quantitative values of clinical test data, making the processing of such data by computers difficult.

Results: We focused on abnormal states in the definition of diseases and proposed a unified form to describe an

abnormal state as a “property,” which can be decomposed into an “attribute” and a “value” in a qualitative representation.

We have developed a three-layer ontological model of abnormal states from the generic to disease-specific level. By

developing an is-a hierarchy and combining causal chains of diseases, 21,000 abnormal states from 6000 diseases have been

captured as generic causal relations and commonalities have been found among diseases across 13 medical departments.

Conclusions: Our results showed that our representation framework promotes interoperability and flexibility of the

quantitative raw data, qualitative information, and generic/conceptual knowledge of abnormal states. In addition, the

results showed that our ontological model have found commonalities in abnormal states among diseases across 13

medical departments.

Keywords: Ontology, Abnormal state, Disease, Property, Attribute, Interoperability

Background: Identifying partial mappings between two terminologies is of special importance when one

terminology is finer-grained than the other, as is the case for the Human Phenotype Ontology (HPO), mainly used

for research purposes, and SNOMED CT, mainly used in healthcare.

Objectives: To investigate and contrast lexical and logical approaches to deriving partial mappings between HPO

and SNOMED CT.

Methods: 1) Lexical approach—We identify modifiers in HPO terms and attempt to map demodified terms to

SNOMED CT through UMLS; 2) Logical approach—We leverage subsumption relations in HPO to infer partial

mappings to SNOMED CT; 3) Comparison—We analyze the specific contribution of each approach and

evaluate the quality of the partial mappings through manual review.

Results: There are 7358 HPO concepts with no complete mapping to SNOMED CT. We identified partial

mappings lexically for 33 % of them and logically for 82 %. We identified partial mappings both lexically and

logically for 27 %. The clinical relevance of the partial mappings (for a cohort selection use case) is 49 % for

lexical mappings and 67 % for logical mappings.

Conclusions: Through complete and partial mappings, 92 % of the 10,454 HPO concepts can be mapped

to SNOMED CT (30 % complete and 62 % partial). Equivalence mappings between HPO and SNOMED CT

allow for interoperability between data described using these two systems. However, due to differences in

focus and granularity, equivalence is only possible for 30 % of HPO classes. In the remaining cases, partial

mappings provide a next-best approach for traversing between the two systems. Both lexical and logical

mapping techniques produce mappings that cannot be generated by the other technique, suggesting

that the two techniques are complementary to each other. Finally, this work demonstrates interesting

properties (both lexical and logical) of HPO and SNOMED CT and illustrates some limitations of mapping

through UMLS.

Keywords: Partial mapping, Human phenotype, Ontology, Standard terminologies, Interoperability

Background: The Biomedical Research Integrated Domain Group (BRIDG) model is a formal domain analysis model

for protocol-driven biomedical research, and serves as a semantic foundation for application and message development

in the standards developing organizations (SDOs). The increasing sophistication and complexity of the BRIDG model

requires new approaches to the management and utilization of the underlying semantics to harmonize domain-specific

standards. The objective of this study is to develop and evaluate a Semantic Web-based approach that integrates the

BRIDG model with ISO 21090 data types to generate domain-specific templates to support clinical study metadata

standards development.

Methods: We developed a template generation and visualization system based on an open source Resource

Description Framework (RDF) store backend, a SmartGWT-based web user interface, and a “mind map” based tool for

the visualization of generated domain-specific templates. We also developed a RESTful Web Service informed by the

Clinical Information Modeling Initiative (CIMI) reference model for access to the generated domain-specific templates.

Results: A preliminary usability study is performed and all reviewers (n = 3) had very positive responses for the

evaluation questions in terms of the usability and the capability of meeting the system requirements (with the

average score of 4.6).

Conclusions: Semantic Web technologies provide a scalable infrastructure and have great potential to enable

computable semantic interoperability of models in the intersection of health care and clinical research.

Keywords: BRIDG, RDF, CIMI, Doman analysis model, Clinical study meta-data standards, Detailed clinical model,

Semantic Web technologies

Data sharing in clinical trials: keeping score

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*The Good Pharma Scorecard is a vital tool in ensuring ethical and responsible data-sharing, say Jennifer E. Miller and Amy Price.*

There are many questions over who should have access to health data and who owns them.  These issues are complicated in clinical trials where data are co-produced by participants, researchers, clinicians, funders, and industry. [Ninety percent of all data ever produced were produced in the past two years](https://www.forbes.com/sites/bernardmarr/2018/05/21/how-much-data-do-we-create-every-day-the-mind-blowing-stats-everyone-should-read/#2b941bc360ba), raising novel ethical questions about the responsibilities of data collectors and the rights of participants. [1] These questions are particularly acute for clinical trial data, which hold life-saving potential and can advance patient and population health.

While many advocate for [enhanced transparency and agency around how health data from electronic health records, wearables,](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719130) [2] and web searches (70-80% of adults search the internet with their health-related questions) are used, this hasn’t been the dominant approach for clinical trial data. Most stakeholders, from patients, [3] to funders,[agree that trial data should be broadly accessible for secondary research purposes](https://www.ncbi.nlm.nih.gov/pubmed/29874542), with some even arguing that they [are a public good](https://www.ncbi.nlm.nih.gov/pubmed/22948695). [4] While expectations around clinical trial data have moved towards greater levels of openness and a sense that data sharing should be a routine part of clinical research,[trial data can remain hidden.](https://www.bmj.com/content/347/bmj.f4794)[5]

We owe it to patients participating in research to make the data they help [generate widely and responsibly available.](https://www.nejm.org/doi/10.1056/NEJMe1601087)[6] The majority desire data sharing, viewing it as [a natural extension of their commitment to advance scientific research](https://www.ncbi.nlm.nih.gov/pubmed/29874542). [3] Data sharing in clinical research is critical to help encourage a host of public health benefits, including facilitating independent re-analysis of data and an improved understanding of a medicine’s safety and efficacy.

Data sharing can also accelerate innovation and the development of new cures and therapies, as scientists learn and build on each other’s work. [Data sharing during the 2014 Ebola virus outbreak](https://academic.oup.com/ve/article/2/1/vew016/1753554) in West Africa, for example, helped scientists rapidly trace the origins of the virus and help control the epidemic. [7,8] Research duplication can also be reduced when resources are pooled through data sharing. For instance, sharing placebo or comparator arm trial data can decrease the number of trial participants needed for future trials of similar compounds. Placebo and comparator arm data have been successfully pooled for use in other trials from the Datasphere Project, the Coalition Against Major Diseases, and ePlacebo. [9]

To resolve this challenge, researchers from Yale University, Stanford University, and Bioethics International, supported by Arnold Ventures, created and validated measures to define good data sharing practices and to benchmark data-sharing practices by pharmaceutical companies. The researchers partnered with key stakeholders including the public and end-users and they collaborated to build the [Good Pharma Scorecard](https://bioethicsinternational.org/good-pharma-scorecard/) (GPS), an annual ranking of new FDA approved drugs and their pharmaceutical company sponsors on their ethics performance, including clinical trial transparency and data-sharing criteria. [Ranking and rating companies](https://www.ncbi.nlm.nih.gov/pubmed/24088150) have long been an evidence-based method for improving corporate behaviors on critical social responsibility goals. [10,11]

[A new research paper](https://www.bmj.com/content/366/bmj.l4217) has found that the [Good Pharma Scorecard rankings](https://bioethicsinternational.org/good-pharma-scorecard/) have improved data-sharing by pharmaceutical companies, as almost half of low scoring companies improved their data-sharing scores within 30 days of receiving their low score. AstraZeneca, for example, newly committed to reporting the number of data requests it receives annually and how each request is handled (i.e. granted or rejected). Novartis committed to sharing trial data by 6 months post approval of a drug or 18 months after the trial is over, when previously it had [no specified timelines for making data available.](https://www.bmj.com/content/366/bmj.l4217)[12] Industry trial registration and results reporting practices are also improving year after year, according to the Good Pharma Scorecard measures. The median proportion of trials in patients with publicly available results at 12 months after FDA approval rose from 87% for 2012 FDA approved drugs to 100% for 2015 drugs.

It is critical to improve drug companies’ data sharing practices, as industry sponsors 90% of the [clinical research for investigational drugs and devices.](http://www.appliedclinicaltrialsonline.com/print/213683?page=full)[13] The GPS data sharing measures require that companies register all applicable trials and have a policy that provides access to datasets which are ready to be analysed, and Clinical Study Reports (CSR). The constitutive elements of a CSR include the statistical analysis plan, study protocol, dataset codebook, and CSR synopsis. The GPS requires companies to clearly state how data may be requested and shared no later than 6 months post FDA or EMA approval of a drug or 18 months after the trial’s completion date. GPS measures require annual reporting on data requests received by companies and whether requests are granted or rejected.

The Good Pharma Scorecard can serve as an agent for change. Patients/carers, clinicians, researchers, policy makers and investors, can require low-scoring companies to commit to reform before working with them. Advocacy groups might demand that companies fix any transparency issues highlighted in the GPS, as a condition for collaborating on participant trial recruitment. Formularies and prescription guideline writers could report the number of trials a company conducts to gain regulatory approval of a drug, and the proportion of those trials that are published in the medical literature.

Empowering stakeholders to be effective at instigating change is one reason the GPS report the scores at both drug and company levels. The GPS provides a unique platform to discuss and address critical ethical challenges raised through healthcare innovation. Given several years of demonstrated impact, it is well poised to tackle other important issues, like drug pricing.

By sharing patient level trial data with the whole research community, we can catalyze the benefits of the resources,[time and effort devoted to clinical trial research and advance patient and population health.](https://www.ahajournals.org/doi/abs/10.1161/CIRCOUTCOMES.112.965798)[14] The Good Pharma Scorecard aims to provide companies with a consistent, fair, and achievable set of measures, while tracking further progress toward routine data sharing in clinical research.

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  Planned experiments -clinical trials, which includes patients and designed to gain insights into the aetiology and progression of diseases as well as to analyse new diagnostic and treatment procedures and in particular to test new drugs [1][2][3], involves many stakeholders from patients [4] to funders. The stakeholders (patients, researchers, clinicians, industry and funders) co-produce data using different standards and vocabulary when reporting the clinical trials.

The vocabularies range from SNOMED-CT, **Logical Observation Identifiers Names and Codes (LOINC),** ICD10, ICD10CM, Medical Subject Heading (MeSH) to the ones that are not standardised.

, The access to these health data raises issues of interoperability of data and effective retrieval of information stored in the various stakeholders data repository due to the many healthcare standards and vocabularies. In [6], it is agreed that data generated by the patients should be responsibly available. However, in the context of RD and the ERNs, they consider a disease to be rare when the number of people affected is less than 5 per 10,000, i.e. 1 out of every 2,000, and there are between 5,000 and 8,000 rare diseases which are mostly genetic based. Rare diseases are serious chronic diseases and may be life-threatening.

Rare diseases (RD) research in the RD care centres comprising of over 27 European Union members, seven associates members and Canada in [European Reference Networks](https://ec.europa.eu/health/ern_en) generates massive data on RD.

The centres are saddled with the responsibility to **decrease unnecessary hardship and prolonged suffering of RD patients, through the various studies on RD and the coordination of the data generated from such studies.**To ***improve***the integration, the efficacy, the production and the social impact of research on RD through the development, demonstration and promotion of Europe/world-wide sharing of research and clinical data, materials, processes, knowledge and know-how.

To ***implement*** and further *develop* an efficient model of financial support for all types of research on RD (basic, clinical, epidemiological, social, economic, health service) coupled with accelerated exploitation of research results for the benefit of patients.

The International Rare Diseases Research Consortium (IRDiRC) was launched in 2011 at the initiative of the European Commission and the U.S. National Institutes of Health with the aim of fostering international collaboration in rare diseases research. However, despite these positive developments, the burden of rare diseases continues to persist for several reasons.

Rare diseases present fundamentally different challenges from those of more common diseases, such as asthma. This is most apparent during the clinical development stage when rarity significantly complicates the task. Problems include the small number of patients, the logistics involved in reaching widely dispersed patients, the lack of validated biomarkers and surrogate end-points, and limited clinical expertise and expert centres.

For many rare diseases, basic knowledge such as the cause of the disease, pathophysiology, natural course of the disease and epidemiological data is limited or not available. This significantly hampers the ability to both diagnose and treat these diseases. To address this challenge, public funding of fundamental research into the disease process remains necessary both at the national and global level. Rare disease patients are scattered across countries. As a result, medical expertise for each of these diseases is a scarce resource. Fragmented disease knowledge means that it is critical that investments in fundamental research go hand-in-hand with investments in dedicated infrastructure and international networks (biobanks, registries, networks of expertise). Where needed, these networks can also provide opportunities to train health professionals on rare diseases. Equally important is the availability of an internationally recognised rare disease classification system which can help generate reliable epidemiological data. Such a system would provide a useful basis for further research into the natural history and causes of rare diseases, and enable monitoring of the safety and clinical effectiveness of therapies and assessment of the quality of care. Ongoing fundamental research into the disease process will result in the discovery of more targets for drug development for a specific rare disease. In particular, public funding of translational research, including proof of concept studies, might act as a catalyst to translate rare disease research into the development of new medicines. Making a disease easy to diagnose at an early stage will allow the development of prevention strategies that, even in the absence of an underlying treatment, can have a significant positive impact on a patient's life. Clinical trial funding programmes remain essential for orphan drug development, especially for rare diseases that appear less attractive for the pharmaceutical industry. Of critical importance for marketing authorisation and reimbursement is the acceptance of the evidence generated during drug development for rare diseases. When the medical need is great, a treatment can become available at an early stage where evidence is robust, but limited. However, this represents a substantial hurdle for some methodological assessments and the development of alternative methods of evaluation in small and very small populations is desirable. Large multidisciplinary networks should be funded to stimulate collaboration and bring together medical experts, reference centres and patients' groups. This infrastructure is necessary for performance of clinical trials and subsequent monitoring of newly authorised products. A new generation of more targeted therapies (such as stem cell therapies, gene therapies or therapeutic gene modulations) is in development and new products are becoming available. To allow these targeted therapies for smaller patient groups to become more common practice, it is critical to continue funding the research and development of these highly innovative therapies. The use of optimised delivery methods (such as controlled or site-specific delivery) could entail improving the pharmacokinetic profiles of existing orphan drugs with improved efficacy, safety profile, or convenience for the patient. Another opportunity for research in pharmacological intervention for rare diseases is to pursue the development of molecules developed for one indication that have also demonstrated potential with a favourable benefit/risk ratio for treating a different rare disorder and could be developed for other indications, a practice known as "drug repurposing". The advantage is that more is known about these molecules and that knowledge can be leveraged in a new development programme.

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