Examples of DUC profiles

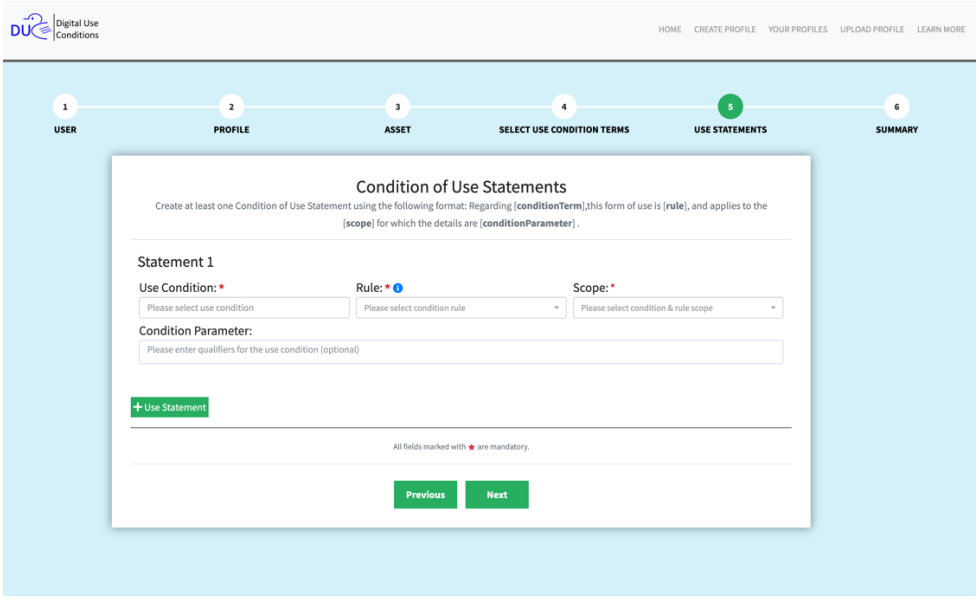
This section gives examples of how to use condition statements in isolation or combination to reflect some “simple” use cases. Even taking these examples into account, it quickly becomes apparent, when used correctly, a profile made using use condition statements can be a powerful tool. However, it should be noted that in the current form there is no logic assumed between each use condition statement and as such each use condition statement in a profile should be treated independently.

Although each use statement is intended to function in isolation from the other use statements in each DUC profile, care must be taken not to create contradictions between use statements the same profile. Currently, it is the responsibility of the user to ensure that this does not occur. While DUC profiles are not intended to be a definitive statement on what uses are possible for a given resource, making them too stringent may preclude a given asset from the search results for a given discovery context.

In basic terms, the use statements take the same form.

Regarding [**conditionTerm**], this form of use is [**rule**] and applies to the [**scope**] for which the details are [**conditionParameter**]

The Conditions of Use Statement box (shown below) in the use statements section (section 5 of the profile tool) can be used to encode the relevant parts of the statement.



It should be noted that adding a condition parameter via free text ***must not*** introduce a duality in a use statement. For example, use inside the EU is permitted but use outside the EU must be subject to GDPR. Similarly, the free text ***must not*** introduce any exceptions, for example use as a control is permitted “except for clinical care”. Such terms should be split so that the exceptions are defined clearly in a separate use statement(s) that states the use(s) that are forbidden.

Examples of Use Statements

The use statement below using the "use by commercial entity" term from CCEs to allow the use by such entities for non-commercial purposes. This example could be useful to allow a commercial entity to use an asset when working on a research project in collaboration with a non-profit institution such as a university.

Regarding [**Commercial Entity**], this form of use is [**Permitted**] and applies to the [**Whole of asset**] for which the details are [**for non-profit use only**]

To ensure that this provision was not abused, a second Use Condition Statement could be constructed that forbid the use of an asset for by a commercial entity for profit purposes (as below)

Regarding [**Commercial Entity**], this form of use is [**Forbidden**] and applies to the [**Whole of asset**] for which the details are [**where the use generates a profit**]

DUO has a term "Disease specific research" which, although not truly atomic is compatible with the DUC schema where the use is intended to be limited to just research on a specific disease or group of them. This can be particularly useful if an asset has been collected with the specific intention that it is to be used to allow research into a specific group of diseases. The use of the obligated rule in the example below, indicates that if this asset is used, it *must* be used for research into neurodegenerative diseases.

Regarding [**Disease specific research**], this form of use is [**Obligated**] and applies to the [**Whole of asset**] for which the details are [**into neurodegenerative diseases**]

In some instances, specific uses may not be widely acceptable to the participants from whom the assets were taken. An example may be the return of incidental findings, which are medically relevant. In such cases it is common for the participants to be asked to give their consent to these findings being returned. To indicate this the "whole of asset" scope term would be changed to "part of asset" (as shown in the example below) to indicate that the "use statement" does not apply to all the samples or records in an asset. Here the CCE term (return of incidental findings) can be used as shown below.

Regarding [**Return Of Incidental Findings**], this form of use is [**Permitted**] and applies to the [**Part of Resource**] for which the details are [**where clinically relevant to the participant and subject to their consent**]

A good example of where restrictions on use can occur is the use of personal data from EU citizens outside the EU. The GDPR stipulates that no matter where the actual processing of these data occur, the individuals to whom they relate must enjoy the same level of data protection as they would if the data were processed inside the EU. CCEs have split the concept of a regulatory jurisdiction and a geographical location as it was found in user

testing the issue of how to stipulate what laws applied were commonly intertwined with the geographical locations where use was permitted. However, there may be instances where even though the use complies with the appropriate set of legal restrictions on use (such as the GDPR) there is a prohibition on using the asset some or all of that location. An example is the prohibition of using patient level data for French citizens outside of France without the appropriate approvals beyond compliance with GDPR. For simplicity if we assume the use outside of France was prohibited then the appropriate "Use Statements" would be.

Regarding [**Regulatory Jurisdiction**], this form of use is [**Obligated**] and applies to the [**Whole of resource**] for which the details are [**use must comply with GDPR**]

Regarding [**Geographical Area**], this form of use is [**Forbidden**] and applies to the [**Whole of resource**] for which the details are [**outside of France**]

In the DUO ontology there is the concept of "informed consent rule". This is defined as "A rule in an informed consent regulatory document that prescribes either an informed consent process or deontic roles inhering in agents that participate in an informed consent process." This can be simplified to a rule in a regulatory document that requires adherence to informed consent. As such although this term is abstracted from the final use, it could be used in DUC to indicate the obligation on the user to obtain informed consent to use an asset for the specific purpose. Usually, this would require recontacting them via the supplying institution. The CCE term "Reidentification of individuals mediated by the resource provider" could be used in conjunction with this term to indicate that use of an asset must be via informed consent, and that this must occur by recontacting the participant via the supplying institution, as shown below.

Regarding [**Informed consent rule**], this form of use is [**Obligated**] and applies to the [**Whole of resource**] for which the details are []

Regarding [**Geographical Area**], this form of use is [**Forbidden**] and applies to the [**Whole of resource**] for which the details are [**outside of France**]

Regarding [**(Re-)Identification Of Individuals Mediated By The Resource Provider**], this form of use is [**Obligated**] and applies to the [**Whole of resource**] for which the details are [**for the purposes of gaining informed consent for proposed use**]

The above example also shows that it is not always necessary to use the condition parameter to provide extra information, hence the reason that this part of the Use Statement is optional.

The use of medical data (particularly generic data) is a sensitive topic for many people, from a country's history to possible implications for the individual and their family. The DUO ontology has several categories of research, to allow rules to be encoded for each one. They include: "Disease specific research", "Health or biomedical research", "Age category research", "Ancestry research", "Biomedical Research", "Drug development research", "Genetic research", "Gender category research", "Method development" and "Population

research". Any of these terms could be used to permit or restrict that particular use for an asset, as shown for "Genetic research" below.

Regarding [**Genetic research**], this form of use is [**Forbidden**] and applies to the [**Whole of resource**] for which the details are [**for the purposes of re-identifying the participant**]

As re-identification of participants in assets that have been anonymised or pseudonymised is usually forbidden (unless mediated by the asset provider for specific purposes, such as to feed back relevant results). However, the level of detail that can be obtained from medical and biological data can produce a unique profile of an individual, that leaves them open to the possibility of being re-identified. The ICO term "looking up a centrally registered identifier" could be used to strictly forbid attempts to reverse coding or pseudonymisation where the recipient would have access to such as database.

Regarding [**looking up a centrally registered identifier**], this form of use is [**Forbidden**] and applies to the [**Whole of resource**] for which the details are [**for the purposes of re-identifying the participant**]