Common Condition of use Elements (CCE)

Explanations Document

Table of contents

1.0 Background.

When in the Virtual Platform researchers are looking for information for their research, will first search for resources that contain resources that match their requirements, then ask for more detail regarding any matching resources that they find before finally submitting an access request to those resources that contain resources that are potentially useful to them.

Registries and biobanks do not give access to everyone who requests it and have restrictions on who they will allow access and the ways in which resources in the resource can be used. Such restrictions are mentioned, for example, in informed consent forms, data access policies and data transfer agreements. To convey these use conditions in an automatised way, the Common Conditions of use Elements (CCE's) have been developed. They will be part of a larger structure DUC (Data Use Conditions) and will be stored and presented in a profile.

A registry or biobank may have more than one profile depending on the different conditions that individual or a collection of resources have within them.

The goal of creating DUC profiles containing CCE statements constructed using CCE terms was not to produce a completely digitised version of the consent and use conditions for a resource (or individual resource), but to gather a broad overview of permissions and use conditions that could answer the typical "What", "Where", "Who" and "When" questions a researcher may ask regarding their intended use, as well as the typical "How" directives that govern the use of such a resource.

Figure 1: The structure of a DUC profile using CCEs

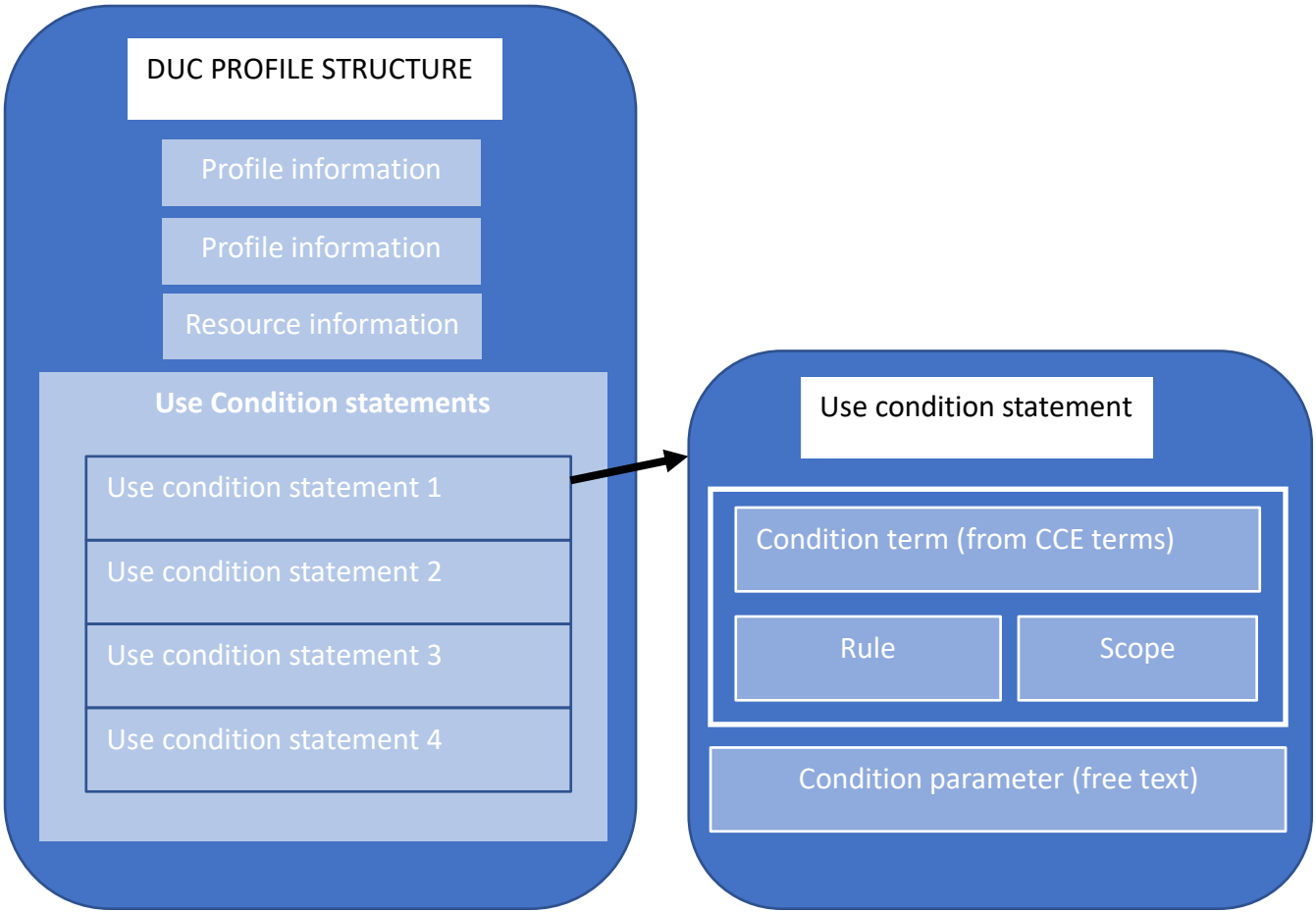

Table 1: DUC resource type definitions

The table below defines the different types that can be assigned to a resource or an individual resource (in the case of dataset or guideline), in section 3 of the DUC tool (see the DUC tool User guide).

Data Level	Description
DATASET	This relates to the direct measurements collected from an experiment or other such observations.
PATIENT REGISTRY	Patient registries are organised systems that use observational methods to collect uniform data on a population defined by a particular disease, condition, or exposure, and that is followed over time. (EMA - Patient registries | European Medicines Agency (europa.eu))
BIOBANK	Biobanks collect and store biological materials that are annotated not only with medical, but often also epidemiological data (e.g., environmental exposures, lifestyle/occupational information). (Biobanks for Europe: A challenge for governance, section 3.1)
GUIDELINE	A document providing guidance on the scientific or regulatory aspects of the development of medicines and applications for marketing authorisation. Although guidelines are not legally binding, applicants need to provide justification for any deviations. (Guideline | European Medicines Agency (europa.eu)

2.0 CCEs used to state Use Condition Terms.

CCE TERMS

CCE terms are used to populate the "Use Condition" section in the DUC schema (shown in figure 1). Each CCE term (element) must have the following characteristics:

- Be **atomic** and capture the information relating to a single aspect or condition of use. For example, "GEOGRAPHICAL AREA" (the location in which a resource can be used).
- Be **non-directional**. To avoid any implication of permission or prohibition.

A "soft" requirement is that they must not address issues that are always resolved in the same manner in the target user group (I.e. use must be stopped if it is based on the consent that is withdrawn). However, a CCE may be desirable where it would be beneficial to state something specifically within a profile, even when it is handled in a near universal manner. This could be especially useful when an expected limitation or requirement of use needed to be specifically exempted (such as the responsibility to feedback incidental findings with clinical significance, due to a patient not consenting to this being the case). Alternatively, the condition detail could be used to expand on required safeguards of use, such as the prevention of cross-linking a dataset to ensure that the prohibition on participant re-identification was preserved.

Table 2 states the current set of CCE terms and gives a description of their meaning.

RULE

Permissions or restrictions relating to the atomic CCE term chosen are set by the end user, using the "CONDITION RULE" dropdown menu. There are 4 rules that can be assigned, and the tool will filter the rules available based on the CCE term selected.

- **FORBIDDEN** – The stated Use/Requirement ***must not*** occur for some or all of the resource
- **PERMITTED** – The stated Use/Requirement ***may*** occur for some or all of the resource
- **OBLIGATED** – The stated Use/Requirement ***must*** occur for some or all of the resource
- **NO REQUIREMENTS –** There is ***no stated requirement*** for the CCE term to be performed during use.

THE RULE SHOULD APPLY TO THE CCE TERM ONLY AND NOT ANY ASSOCIATED CONDITION ELEMENTS.

PERMITTED VS OBLIGATORY RULES

A "PERMITTED" use may occur but does ***not*** have compulsory element. Further, the "PERMITTED" rule should also be used when use is allowed in a selected set of circumstances (I.e. there are conditions attached). The "OBLIGATED" rule should be used where a resource ***must*** be used in a certain way, for example a resource may only be available for use relating to a specific disease, hence the CCE term "disease specific use" would be selected and the "OBLIGATORY" rule would be set, with the specific disease(s) being stated as free text in the "condition details" field

SCOPE

Once a CCE term and its rule have been defined for a resource, the user must define the “SCOPE” (or extent) to which the CCE term applies to that resource by selecting one of the following two self-explanatory options.

- **WHOLE OF RESOURCE**
- **PART OF RESOURCE**

CONDITION DETAILS

Following this the user can then add additional information, which relates to how the full use statement applies to the resource in the condition details box.

Comments Regarding CCE box

This box is a free text field that allows users to make comments about either the tool or any aspect of the CCE framework itself.

Table 2: CCE Terms Definitions

Concept	Definition
Commercial Entity	Use by an entity in the commercial sector, whether or not that use seeks to make a financial profit.
Geographical Area	Use within specified geographic region(s)
Regulatory Jurisdiction	Use within an area defined by a shared legal framework, or subject to a common oversight organisation.
Research Use	Use for research-related exploration or innovation.
Clinical Care Use	Use for patient healthcare and related services.
Medical Research Use	Use for research-related activities that involve human subjects where the intention is to advance medical knowledge.
Disease Specific Use	Use for research-related activities pertaining to one or more specific diseases or disease categories.
Use As Control	Use as a reference, benchmark or normal control for research or other activities.
Profit Motivated Use	Use with the intention of making profit.
Time Period	Use that has some time-frame limitation.
Collaboration	Use that involves some form of collaboration, typically with the resource provider.
Fees	Use that involves payment as a basis for the access or use.
Return Of Results	Use that involves a requirement on the recipient to return results that were intentionally generated by the planned use, to the resource provider.
Return Of Incidental Findings	Use that involves a requirement on the recipient to return results that were not intentionally generated by the planned use, to the resource provider.
(Re-)Identification Of Individuals Without Involvement Of The Resource Provider	Use of records or samples in a resource (provided in a non-identified form) in a manner that identifies or re-identifies one or more individuals, without the involvement of the resource provider.
(Re-)Identification Of Individuals Mediated By The Resource Provider	Use of records or samples in a resource (provided in a non-identified form) in a manner that identifies or re-identifies one or more individuals, mediated with the involvement of the resource provider
Publication Moratorium	Use involves a requirement on the recipient to not publish derived results before a specific date, time period, or other condition (such as approval from the supplying institution) has been met.
Publication	Use involves a requirement on the recipient to make derived results available to the wider scientific community.
User Authentication	Use involves a requirement on the recipient to successfully undertake some form of ID proofing and authentication, prior to the access or use.
Ethics Approval	Use involves a requirement on the recipient to evidence suitable ethics board (e.g., IRB/ERB) or other intuitional or oversight body approval.

Rules for completing condition details in order to minimise CCE statement complexity.

In order to keep the atomic nature of a CCE term when adding free text to the condition detail in the CCE statement, the free text should conform to the following rules.

- Not make a conditional statement (i.e. “permitted” *except for…*)
- Not create duality in the rule (i.e. permitted in the EU and outside the EU subject to GDPR).

- Not create interdependencies of CCE statements

The user is also reminded that currently there is not implied logic between CCE statements by default. Hence, each should be treated independently. It is recommended that a separate profile is created for each intended use of a resource for greater clarity over which terms apply to which use.

Examples of the use of free text to elaborate CCE terms.

For each CCE statement it is possible to include additional free text in the condition details in order to elaborate on the specifics of a given CCE term. While the use of free text is entirely optional, there are certain CCEs where it can be highly beneficial, particularly if the CCE statements are viewed separately to the main profile. Some examples are included in table 3 below.

Table 3: Examples of using condition details free text to elaborate CCE terms.

CCE term	Examples of free text elaborations.
Commercial Entity	Research use only
Geographical Area	Country or region
Regulatory Jurisdiction	Country or region Example: French law applies. Regulatory requirement that applies over wider or more generic area than a geographically defined one e.g. GDPR applies (to indicate an additional requirement to use outside of a regulatory region, in this case the EU) Use outside xxxx is subject to participant consent
Research Use	Specifying a given type of area of research for permission or prohibition This may also by subject to informed consent
Clinical Care Use	Excluding types of clinical care such (using the forbidden rule) such as: transplantation, administration as a drug or treatment
Medical Research Use	Excluding different types of research (via the forbidden rule) such as *in vivo* trials on humans.
Disease Specific Use	Stating the disease or disease areas that are either permitted of prohibited (such as HIV research was prohibited when using PCR when it was still in patent). Subject to participant's informed consent
Profit Motivated Use	To exclude (using the forbidden rule) certain types of profit motivated use such as: sale to third parties. offered or used as part of a commercial service. Or to state a condition on this type of use such as subject to participant's informed consent.

Use As Control	Free text could be used to limit this utility (via the forbidden rule) such as: Use in diagnostics For resale / commercial use Or to add a condition for this type of use such as for research use only
Re-)Identification Of Individuals Without Involvement Of The Resource Provider	It is expected that this CCE term will largely be prohibited outright, as in countries such as the UK there are specific laws (i.e. the 2018 data protection act) which specifically prohibit the reidentification of data provided in a non-identifiable format. However, it could be used to explicitly state situations where there are presidents that permit this, such as for the purposes of law enforcement, medical intervention (although this is typically via the resource supplier) Alternatively, it could be used to specify the need for an action plan in the event of accidental re-identification (used with forbidden rule) or to specify the required safeguards required to ensure this does not happen in the condition details.
(Re-)Identification Of Individuals Mediated By The Resource Provider	This is a more typical method of re-identification, for example for the purposes of re-contacting a participant, requesting extra samples or feeding back clinically relevant information via the resource provider.
Time Period	Free text could be used to specify an exact date or time period for use after receipt of the resource had occurred. For example: “For up to 12 months after receipt” “Up to 3 months after the project’s end date.” This term can also be expanded to include information on what should be done with excess material after the time period has elapsed e.g.: “Excess material must be returned to the provider” “Excess material must be destroyed”. Alternatively, this CCE term can be expanded with free text that defines a set of conditions that must be met to either permit continued use (e.g. for the duration of the approved

	project) or that define an end point to it (e.g. while stocks last).
Collaboration	The free text can be used to specify who the recipient must collaborate with and any restrictions around doing so e.g. "The recipient agrees to work with the resource provider on projects that overlap with its core work in xxxx" "The recipient agrees to inform the resource provider of any collaboration and await their approval before proceeding".
Fees	The free text can be used to give details of the fees, examples may include: "The recipient agrees to pay packing and shipping costs to the provider".
Return of results	The free text can be used to specify when and how this should happen. For example: "The recipient agrees to share the results of their work with the resource provider before publication" "The recipient agrees to return all clinically actionable findings to the resource provider subject to participant's informed consent"
Return of incidental findings	The free text can be used to specify when and how this should happen. For example: "The recipient agrees to share incidental findings of their work with the supplying institution before publication" "The recipient agrees to return all clinically actionable findings to the supplier subject to participant's informed consent".
Publication moratorium	The free text can be used to set a time limit or a requirement to seek approval for publication from the supplier before publication.
Publication	The free text can be used to specify that results must be published and any conditions surrounding this. For example: "The recipient agrees to publish their findings in an open access journal". Alternatively, the free text can be used to place an obligation on the publication for example: "the recipient agrees to acknowledge the supplier in all publications".
User authentication	The free text can be used to specify what type of authentication is required. For example: "The user must provide a valid researcher ID via service xxxxx in order to register with the providing institution"

	"The user must register with a validated email address from a recognised research institution".
Ethics Approval	Free text can be used to specify the type of approval required. For example: "The user must provide their IRAS application number and approvals" (for a UK based provider).

Repeated concepts in free text.

Please note that there are some common phrases that are already apparent as listed below

- Use permitted only where GDPR is respected
- Subject to informed consent
- For research use only
- For diagnostic purposes
- For cost recovery
- Subject to approval by access or ethics committee of the resource provider
- Please try to use common country and region names without full stops (e.g. EU, UK or USA).

This list will be expanded as more profiles are submitted; it is hoped that this will help to standardise the free text somewhat to make subsequent use of the profiles easier, due to an increased uniformity in the free text. Please feel free to send us any short standard phrases you have found yourself using repeatedly in use condition statements so that we can consider adding them to the above list. As these phrases are more specific or expansions of existing CCEs, currently they are not being considered for becoming CCEs in their own right.