The ECX Document Format — Version 1.3

An ecx document is a ZIP file that contains a single [JSON](#) encoded data file (*data.json*) and any number of auxiliary data files. The zip container MAY use compression.

The current specification only uses data files for attached documents. They SHOULD be stored below an *attachments/* directory inside the ZIP archive. JSON fields that have a `null` value, MAY be ommitted from the document.

The suggested file extension is *ecx*, the mimetype *application/ecx*.

data.json

`"version"`: STRING, MUST be "1.3"
`"type"`: STRING, MUST be "`SubmissionForm`"
`"data"`: OBJECT
    {
    `"additional_therapy_info"`: STRING (6.3 Additional information on study-related activities and any necessary deviations from the routine treatment)
    `"already_voted"`: BOOLEAN (2.8 There are already votes of other ethics commissions.)
    `"clinical_phase"`: STRING max. 10 characters, may be null (2.5 Clinical Phase)
    `"created_at"`: STRING RFC 3339 with timezone UTC+1 (e.g. 2010-07-14T16:04:35+01:00)
    `"documents"`: OBJECT[]
        {
        `"date"`: STRING RFC 3339 with timezone UTC+1 (e.g. 2010-07-14T16:04:35+01:00) (date of document creation)
        `"doctype"`: STRING - choices:

            `"Covering Letter"`
                Covering Letter
            `"patient information"`
                patient information
            `"insurancecertificate"`
                insurancecertificate
            `"study protocol"`
                study protocol
            `"Investigator's Brochure"`
                Investigator's Brochure
            `"Amendment"`
                Amendment
            `"Curriculum Vitae (CV)"`
                Curriculum Vitae (CV)

"Conflict of Interest"
            Conflict of Interest
        "Case Report Form (CRF)"
            Case Report Form (CRF)
        "EudraCT Form"
            EudraCT Form
        "adverse reaction report"
            adverse reaction report
        "Statement on a review"
            Statement on a review
        "Questionnaire"
            Questionnaire
        "Signed Page"
            Signed Page
        "Manual"
            Manual
        "Declaration of conformity"
            Declaration of conformity
        "other"
            other
        "Submission Form"
            Submission Form
        "Checklist"
            Checklist
        "vote"
            vote
        "Notification"
            Notification
        "Notification Answer"
            Notification Answer
        "Invoice"
            Invoice
        "Checklist Payment"
            Checklist Payment
        "Meeting Protocol"
            Meeting Protocol
        "Meeting ZIP"
            Meeting ZIP

    "mimetype": STRING max. 100 characters
    "name": STRING max. 250 characters
    "original_file_name": STRING max. 250 characters, may be null (
    file name)
    "version": STRING max. 250 characters (version)
    }
"eudract_number": STRING max. 60 characters, may be null (1.2.1
EudraCT-Nr.)
"foreignparticipatingcenter_set": OBJECT[]
    {
    "investigator_name": STRING max. 60 characters (investigator)
    "name": STRING max. 60 characters (name)
    }

```
"german": OBJECT
    {
    "abort_info": STRING may be null (7.19 Rules for the suspension
    or premature termination of the study at the test center, at the
    Member State or the entire study)
    "additional_info": STRING may be null (7.22 additional
    information)
    "aftercare_info": STRING may be null (7.17 Plan for treatment or
    care after the person has completed their participation in the study)
    "benefits_info": STRING may be null (7.11 Expected benefits for
    the included test participants)
    "concurrent_study_info": STRING may be null (7.13 Procedures
    on the site, to determine whether a person at a time to be included in
    another study, participate or whether a required period of time has
    elapsed since a participation in another study)
    "consent_info": STRING may be null (7.9 Approach at test center
    (s), for informing and obtaining an informed consent of candidates)
    "dataaccess_info": STRING may be null (7.20 Agreement on
    access of the examiner(s) to data, publication guidelines, etc)
    "dataprotection_info": STRING may be null (7.16 Methods used
    to protect the confidentiality of the data collected, the source
    documents and the samples)
    "ethical_info": STRING may be null (7.6 ethical considerations)
    "financing_info": STRING may be null (7.21 Financing of the
    study and information on financial or other interests of the examiner)
    "inclusion_exclusion_crit": STRING may be null (7.5 Relevant
    in- and exclusion criteria)
    "payment_info": STRING may be null (7.18 Amount and method of
    compensation or remuneration to the test participants)
    "preclinical_results": STRING may be null (7.3 Results of pre-
    clinical tests or justification for the waiving of pre-clinical tests)
    "primary_hypothesis": STRING may be null (7.4 Primary
    hypothesis of the study)
    "project_title": STRING may be null (7.1 project title (kraut-
    speak))
    "protected_subjects_info": STRING may be null (7.7 Justification
    for the inclusion of persons from protected groups)
    "recruitment_info": STRING may be null (7.8 Description of the
    recruitment process)
    "relationship_info": STRING may be null (7.12 Relation between
    subject and investigator)
    "risks_info": STRING may be null (7.10 Risk assessment)
    "sideeffects_info": STRING may be null (7.14 Methods to
    identify, record, and report undesirable effects)
    "statistical_info": STRING may be null (7.15 Statistical
    considerations and reasons for the number of people who should be
    included in the study)
    "summary": STRING may be null (7.2 project summary)
    }
"insurance": OBJECT
    {
    "address": STRING max. 80 characters, may be null (5.1.2 address)
```

```
    "contract_number": STRING max. 60 characters, may be null (5.1.4
    policy number)
    "name": STRING max. 125 characters, may be null (5.1.1 insurance
    company)
    "not_required": BOOLEAN ( No insurance is required)
    "phone": STRING max. 30 characters, may be null (5.1.3 phone)
    "validity": STRING max. 60 characters, may be null (5.1.5 validity)
    }
"investigators": OBJECT[]
    {
    "certified": BOOLEAN (10.9 certified)
    "contact_first_name": STRING max. 30 characters (10.1 first
    name of the Investigator)
    "contact_gender": STRING max. 1 characters, may be null (10.1
    salutation of the Investigator) - choices:

        "f"
            Ms
        "m"
            Mr

    "contact_last_name": STRING max. 30 characters (10.1 last name
    of the Investigator)
    "contact_title": STRING max. 30 characters (10.1 title of the
    Investigator)
    "email": STRING max. 254 characters (10.6 e-mail)
    "employees": OBJECT[]
        {
        "firstname": STRING max. 40 characters ( first name)
        "organisation": STRING max. 80 characters ( Institution)
        "sex": STRING max. 1 characters ( Ms/Mr) - choices:

            "m"
                Mr
            "f"
                Ms

        "surname": STRING max. 40 characters ( last name)
        "title": STRING max. 40 characters ( title)
        }
    "ethics_commission": STRING - choices:

    "23d805c6b5f14d8b9196a12005fd2961"
        Ethikkommission der Medizinischen Universität Wien
    "7b51f38bde8a4161a0dc34647fc7e654"
        Ethikkommission Krankenhaus Barmh.Brüder - Wien
    "85dc386061584fbe8549ce4e4d828fbd"
        Ethikkommission der Stadt Wien gemäß KAG, AMG und
        MPG
    "d6a22c635a584521b107481ac18318f6"
        Ethikkommission Forschungsinstitut des Wiener Roten
        Kreuzes
```

"55ae93ec9df04d6abfc8d233ec5ccf8e"
    Nicht verwenden: Ethikkommission Krankenhaus
    Barmh.Schwestern - Wien
"7cd6d52120b3474ba502931b9f60a5f3"
    Ethikkommission Confraternität-Priv.Klin. Josefstadt und
    Priv.Klin. Döbling
"7df9ebaf15434709b09c3def9a6c8769"
    Ethikkommission St.Anna Kinderspital
"f122f144616541d391fde2dcc761aff4"
    Ethikkommission Österreichische Arbeitsgemeinschaft für
    Klinische Pharmakologie
"25b6744780434a3f96a1e43b405d3848"
    Ethikkommission Privatkrankenanstalt Rudolfinerhaus
"d542994ced34403db841786a1c1ab892"
    Ethikkommission Rheuma-Zentrum Wien-Oberlaa
"5615dfbaf8c8445d960d1e2cd9c00dc3"
    Nicht verwenden: Ethikkommission Krankenhaus des
    Göttlichen Heilandes
"4d3a2d5f138940f293ee87fe6ec1d5b2"
    Ethikkommission Evangelisches Krankenhaus
"8d2950e3a0294f68bde647a54df6d823"
    Ethikkommission der Allgemeinen
    Unfallversicherungsanstalt
"9f6b509e716e413f865d95bdd630e9bc"
    Ethikkommission Immunologische Tagesklinik
"b17f32f604fa4452b5ff3a2baa9e0704"
    Ethikkommission des Landes Niederösterreich
"6688ce16a3b84d42b1531389e6039891"
    Ethikkommission Krankenhaus Elisabethinen
"e4dcd05a31ad475ca72dea7b84ef030e"
    Ethikkommission des Landes Oberösterreich
"e269491bb9c040aaad6a5f11df343f38"
    Ethikkommission Krankenhaus Barmh.Brüder - Linz
"1cca34032077445d95dabf7802fade28"
    Ethikkommission Krankenhaus Barmh.Schwestern - Linz
"39cbb589ef044d27bceb6ee5ac796ae7"
    Ethikkommission für das Bundesland Salzburg
"280414583b894c809a9baa8134d7fe4b"
    Ethikkommission der Medizinischen Universität Innsbruck
"183881da8200493aa7edd8bebeea75b9"
    Ethikkommission des Landes Vorarlberg
"95821eba88f34b2195f96e747d7f6b16"
    Ethikkommission des Landes Burgenland gemäß KAG, AMG
    und MPG
"6e7cfab5f8cd40df83c9de4fac9bb20f"
    Ethikkommission des Landes Steiermark gemäß AMG und
    MPG
"75b5a9714f354a5b842aa01029148036"
    Ethikkommission Krankenhaus Barmh.Brüder - Graz
"9287fb0878b94f9f9d90b5582d1cefca"
    Ethikkommission Krankenhaus Barmh.Brüder - Eggenberg
"e17ee744e4e840778f316cf3f79de6b4"

Ethikkommission der Medizinischen Universität Graz
"ec9f179a52a04a7aa52446232c3fd4bd"
Ethikkommission des Landes Kärnten
"c890205dcb7543c8a76bf324512c5f81"
Nicht verwenden: Ethikkommission des Krankenhaus St.
Josef
"dc1b115d9809461ba3ea9450b079ddd6"
Kommission für Scientific Integrity und Ethik der Karl
Landsteiner Privatuniversität
"50dba0126a0746dc8802e6c0e0199dad"
Ethik-Kommission der Vinzenz Gruppe Wien

"fax": STRING max. 30 characters (10.5 FAX)
"jus_practicandi": BOOLEAN (10.7 Jus practicandi)
"main": BOOLEAN (principal investigator)
"mobile": STRING max. 30 characters (10.4 mobile)
"organisation": STRING max. 80 characters (10.2 study site)
"phone": STRING max. 30 characters (10.3 phone)
"specialist": STRING max. 80 characters (10.8 specialist for)
"subject_count": INTEGER (11. number of participants)
}
"invoice": OBJECT
{
"address": STRING max. 60 characters, may be null (1.5.2 address)
"city": STRING max. 80 characters, may be null (1.5.2 city)
"contact_first_name": STRING max. 30 characters (1.5.3 first
name of contact person)
"contact_gender": STRING max. 1 characters, may be null (1.5.3
sex of contact person) - choices:

"f"
Ms
"m"
Mr

"contact_last_name": STRING max. 30 characters (1.5.3 last name
of contact person)
"contact_title": STRING max. 30 characters (1.5.3 title of contact
person)
"email": STRING max. 254 characters, may be null (1.5.6 e-mail)
"fax": STRING max. 45 characters, may be null (1.5.5 fax)
"name": STRING max. 160 characters, may be null (1.5.1 invoice
name)
"phone": STRING max. 50 characters, may be null (1.5.4 telephone)
"uid": STRING max. 35 characters, may be null (1.5.7 UID-Number)
"zip_code": STRING max. 10 characters, may be null (1.5.2 postal
code)
}
"measures": OBJECT[]
{
"category": STRING max. 3 characters (study reference) - choices:

"6.1"
            only study-related
        "6.2"
            for routine purposes

    "count": STRING max. 150 characters (number/dose)
    "period": STRING max. 30 characters (period)
    "total": STRING max. 30 characters (total)
    "type": STRING max. 150 characters (type)
    }
"medtech": OBJECT
    {
    "ce_symbol": STRING may be null (4.5 The medical product carries
    a CE mark)
    "certified_for_exact_indications": STRING may be null (4.3
    Certified for this indication)
    "certified_for_other_indications": STRING may be null (4.4
    Certified, but for another indication)
    "checked_product": STRING may be null (2.4.1 Test products(e))
    "departure_from_regulations": STRING may be null (4.8 Any
    deviations from the above provisions (standards))
    "manual_included": STRING may be null (4.6 The product brochure
    is included.)
    "manufacturer": STRING max. 80 characters, may be null (4.2
    Manufacturer)
    "product_name": STRING max. 210 characters, may be null (4.1
    Name of the product)
    "reference_substance": STRING may be null (2.4.2 reference
    product)
    "technical_safety_regulations": STRING may be null (4.7 What
    rules or standards have been used for the construction and testing of
    the medical product (technical safety))
    }
"nontesteduseddrug_set": OBJECT[]
    {
    "dosage": STRING max. 40 characters (dosage)
    "generic_name": STRING max. 40 characters (Generic Name)
    "preparation_form": STRING max. 40 characters (dosage Form)
    }
"participatingcenternonsubject_set": OBJECT[]
    {
    "ethics_commission": STRING - choices:

        "23d805c6b5f14d8b9196a12005fd2961"
            Ethikkommission der Medizinischen Universität Wien
        "7b51f38bde8a4161a0dc34647fc7e654"
            Ethikkommission Krankenhaus Barmh.Brüder - Wien
        "85dc386061584fbe8549ce4e4d828fbd"
            Ethikkommission der Stadt Wien gemäß KAG, AMG und
            MPG
        "d6a22c635a584521b107481ac18318f6"

Ethikkommission Forschungsinstitut des Wiener Roten Kreuzes
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Nicht verwenden: Ethikkommission Krankenhaus Barmh.Schwestern - Wien
"7cd6d52120b3474ba502931b9f60a5f3"
Ethikkommission Confraternität-Priv.Klin. Josefstadt und Priv.Klin. Döbling
"7df9ebaf15434709b09c3def9a6c8769"
Ethikkommission St.Anna Kinderspital
"f122f144616541d391fde2dcc761aff4"
Ethikkommission Österreichische Arbeitsgemeinschaft für Klinische Pharmakologie
"25b6744780434a3f96a1e43b405d3848"
Ethikkommission Privatkrankenanstalt Rudolfinerhaus
"d542994ced34403db841786a1c1ab892"
Ethikkommission Rheuma-Zentrum Wien-Oberlaa
"5615dfbaf8c8445d960d1e2cd9c00dc3"
Nicht verwenden: Ethikkommission Krankenhaus des Göttlichen Heilandes
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Ethikkommission Evangelisches Krankenhaus
"8d2950e3a0294f68bde647a54df6d823"
Ethikkommission der Allgemeinen Unfallversicherungsanstalt
"9f6b509e716e413f865d95bdd630e9bc"
Ethikkommission Immunologische Tagesklinik
"b17f32f604fa4452b5ff3a2baa9e0704"
Ethikkommission des Landes Niederösterreich
"6688ce16a3b84d42b1531389e6039891"
Ethikkommission Krankenhaus Elisabethinen
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Ethikkommission Krankenhaus Barmh.Schwestern - Linz
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"280414583b894c809a9baa8134d7fe4b"
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"95821eba88f34b2195f96e747d7f6b16"
Ethikkommission des Landes Burgenland gemäß KAG, AMG und MPG
"6e7cfab5f8cd40df83c9de4fac9bb20f"
Ethikkommission des Landes Steiermark gemäß AMG und MPG
"75b5a9714f354a5b842aa01029148036"
Ethikkommission Krankenhaus Barmh.Brüder - Graz
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Ethikkommission Krankenhaus Barmh.Brüder - Eggenberg
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Ethikkommission der Medizinischen Universität Graz
"ec9f179a52a04a7aa52446232c3fd4bd"
Ethikkommission des Landes Kärnten
"c890205dcb7543c8a76bf324512c5f81"
Nicht verwenden: Ethikkommission des Krankenhaus St. Josef
"dc1b115d9809461ba3ea9450b079ddd6"
Kommission für Scientific Integrity und Ethik der Karl Landsteiner Privatuniversität
"50dba0126a0746dc8802e6c0e0199dad"
Ethik-Kommission der Vinzenz Gruppe Wien

"investigator_name": STRING max. 60 characters (investigator)
"name": STRING max. 60 characters (name)
}
"pharma_checked_substance": STRING may be null (2.3.1 Test substances)
"pharma_reference_substance": STRING may be null (2.3.2 Reference substance)
"project_title": STRING (1.1 project title (english))
"project_type": OBJECT
{
"basic_research": BOOLEAN (2.1.5 Non-therapeutic biomedical research involving human subjects (basic research))
"biobank": BOOLEAN (2.1.11 Biobank)
"education_context": INTEGER may be null (2.1.8/9 Dissertation / Thesis) - choices:

1
Dissertation
2
Diplomarbeit

"gender_medicine": BOOLEAN (2.1.17 Gender medicine)
"genetic_study": BOOLEAN (2.1.6 Genetic survey)
"medical_device": BOOLEAN (2.1.4 Clinical investigation of medical devices)
"medical_device_performance_evaluation": BOOLEAN (2.1.4.3 Performance evaluation (in-vitro diagnostics))
"medical_device_with_ce": BOOLEAN (2.1.4.1 with CE-marking)
"medical_device_without_ce": BOOLEAN (2.1.4.2 without CE-marking)
"medical_method": BOOLEAN (2.1.3 Clinical testing of a new medical method)
"misc": STRING may be null (2.1.7 Other, please specify)
"non_interventional_study": BOOLEAN (2.1.16 Non-interventional Study (NIS))
"non_reg_drug": BOOLEAN (2.1.1 Clinical trial of an unregistered drug)
"nursing_study": BOOLEAN (2.1.15 Nursing Scientific Study)

"psychological_study": BOOLEAN (2.1.14 Psychological study)
        "questionnaire": BOOLEAN (2.1.13 Questionnaire investigation)
        "reg_drug": BOOLEAN (2.1.2 Clinical testing of a registered product)
        "reg_drug_not_within_indication": BOOLEAN (2.1.2.2 not according to the indication)
        "reg_drug_within_indication": BOOLEAN (2.1.2.1 according to the indication)
        "register": BOOLEAN (2.1.10 Register)
        "retrospective": BOOLEAN (2.1.12 Retrospective data analysis)
        }
    "specialism": STRING may be null (2.2 special field)
    "sponsor": OBJECT
        {
        "address": STRING max. 60 characters, may be null (1.5.2 address)
        "city": STRING max. 80 characters, may be null (1.5.2 city)
        "contact_first_name": STRING max. 30 characters (1.5.3 first name of contact person)
        "contact_gender": STRING max. 1 characters, may be null (1.5.3 sex of contact person) - choices:

            "f"
                Ms
            "m"
                Mr

        "contact_last_name": STRING max. 30 characters (1.5.3 last name of contact person)
        "contact_title": STRING max. 30 characters (1.5.3 title of contact person)
        "email": STRING max. 254 characters, may be null (1.5.6 e-mail)
        "fax": STRING max. 30 characters, may be null (1.5.5 fax)
        "name": STRING max. 100 characters, may be null (1.5.1 sponsor name)
        "phone": STRING max. 30 characters, may be null (1.5.4 telephone)
        "uid": STRING max. 35 characters, may be null (1.5.7 UID-Number)
        "zip_code": STRING max. 10 characters, may be null (1.5.2 postal code)
        }
    "study_plan": OBJECT
        {
        "abort_crit": STRING max. 265 characters, may be null (8.3.3 Termination criteria)
        "alpha": STRING max. 80 characters (8.2.1 Alpha)
        "alpha_sided": INTEGER may be null ( ) - choices:

            0
                single-sided
            1
                double-sided

`"alternative_hypothesis"`: STRING may be null (8.1.21 alternative hypothesis)

`"biometric_planning"`: STRING max. 260 characters (8.5.1 Who did the biometric planning (if applicable, proof of qualification)?)

`"blind"`: INTEGER (Open / Blind / Double-blind) - choices:

    `0`

        open

    `1`

        blind

    `2`

        double-blind

    `3`

        not applicable

`"controlled"`: BOOLEAN (8.1.6 controlled)

`"cross_over"`: BOOLEAN (8.1.7 cross-over)

`"datamanagement"`: STRING (8.4.2 Information on data management)

`"dataprotection_anonalgoritm"`: STRING may be null (8.6.3 How is the anonymization done?)

`"dataprotection_choice"`: STRING max. 15 characters (8.6.1 Information privacy) - choices:

    `"personal"`

        individual-related

    `"non-personal"`

        implicit individual-related

    `"anonymous"`

        completely anonymous

`"dataprotection_dvr"`: STRING max. 180 characters, may be null (8.6.2 DPR-Nr.)

`"dataprotection_reason"`: STRING max. 120 characters, may be null (8.6.2 Justification)

`"dataquality_checking"`: STRING (8.4.1 Information on the data quality audit)

`"dropout_ratio"`: STRING max. 80 characters (8.2.5 Expected number of study dropouts(Drop-out-Quota))

`"equivalence_testing"`: BOOLEAN (8.1.14 equivalence testing)

`"factorized"`: BOOLEAN (8.1.11 factorized)

`"interim_evaluation"`: BOOLEAN (8.3.3 Interim evaluation)

`"misc"`: STRING may be null (8.1.15 misc)

`"multiple_test"`: BOOLEAN (8.2.4 multiple testing)

`"multiple_test_correction_algorithm"`: STRING max. 100 characters, may be null (8.2.4 correctionalgorithm)

`"null_hypothesis"`: STRING may be null (8.1.20 null hypothesis)

`"number_of_groups"`: STRING may be null (8.1.16 number of groups)

`"observer_blinded"`: BOOLEAN (8.1.13 observer-blinded)

`"parallelgroups"`: BOOLEAN (8.1.3 parallel groups)

`"pilot_project"`: BOOLEAN (8.1.12 pilot project)

```
    "placebo": BOOLEAN (8.1.10 placebo)
    "planned_statalgorithm": STRING may be null (8.3.4 Planned use
    of statistical methods)
    "population_intention_to_treat": BOOLEAN (8.3.1 Intention-to-
    treat)
    "population_per_protocol": BOOLEAN (8.3.2 Per Protocol)
    "power": STRING max. 80 characters (8.2.2 Power)
    "primary_objectives": STRING may be null (8.1.19 primary
    objectives)
    "randomized": BOOLEAN (8.1.2 randomized)
    "sample_frequency": STRING may be null (8.1.18 sample
    frequency)
    "secondary_objectives": STRING may be null (8.1.22 secondary
    objectives)
    "statalgorithm": STRING max. 80 characters (8.2.3 statistical
    algorithm)
    "statistics_implementation": STRING max. 270 characters (8.5.2
    Who will conduct the statistical analysis (if applicable, proof of
    qualification)?)
    "stratification": STRING may be null (8.1.17 stratification)
    }
"subject": OBJECT
    {
    "childbearing": BOOLEAN (2.10.5 women of childbearing age)
    "count": INTEGER (2.9 Planned number of trial participants total)
    "duration": STRING max. 200 characters (2.11 Duration of
    participation of the individual test participants in the study)
    "duration_active": STRING max. 200 characters (2.11.1 active
    phase)
    "duration_controls": STRING max. 200 characters, may be null
    (2.11.2 Follow-up inspections)
    "females": BOOLEAN (2.10.4 female participants)
    "males": BOOLEAN (2.10.4 male participants)
    "maxage": INTEGER may be null (2.10.2 maximum age)
    "minage": INTEGER may be null (2.10.1 minimum age)
    "noncompetents": BOOLEAN (2.10.3 non competent participants)
    "planned_total_duration": STRING max. 250 characters (2.12
    Expected total duration of the study)
    }
"submission": OBJECT
    {
    "ec_number": INTEGER
    }
"submission_type": INTEGER may be null ( Submit as) - choices:

    1
        monocentric
    2
        multicentric, main ethics commission
    6
        multicentric, local ethics commission
```

"submitter": OBJECT
{
"contact_first_name": STRING max. 30 characters (9.1 first name)
"contact_gender": STRING max. 1 characters, may be null (9.1 salutation) - choices:

    "f"
        Ms
    "m"
        Mr

"contact_last_name": STRING max. 30 characters (9.1 last name)
"contact_title": STRING max. 30 characters (9.1 title)
"email": STRING max. 254 characters, may be null (e-mail)
"is_authorized_by_sponsor": BOOLEAN (9.4.4 The submitter is a person/organization authorized by the sponsor)
"is_coordinator": BOOLEAN (9.4.1 The submitter is a coordinating examiner (multicentric study))
"is_main_investigator": BOOLEAN (9.4.2 The submitter is a principal investigator (monocentric study))
"is_sponsor": BOOLEAN (9.4.3 The submitter is a sponsor / representative of the sponsor)
"jobtitle": STRING max. 130 characters (9.3 position)
"organisation": STRING max. 180 characters (9.2 Institution / Company)
}
"substance": OBJECT
{
"p_c_t_application_type": STRING max. 145 characters, may be null (3.2.4 application type(s))
"p_c_t_countries": STRING[] max. 2 characters (3.2.1 3.2.1 Countries in which the tests were conducted) - choices:

    "AF"
        Afghanistan
    "AX"
        Åland Islands
    "AL"
        Albania
    "DZ"
        Algeria
    "AS"
        American Samoa
    "AD"
        Andorra
    "AO"
        Angola
    "AI"
        Anguilla
    "AQ"
        Antarctica
    "AG"

Antigua and Barbuda

"AR"

Argentina

"AM"

Armenia

"AW"

Aruba

"AU"

Australia

"AT"

Austria

"AZ"

Azerbaijan

"BS"

Bahamas

"BH"

Bahrain

"BD"

Bangladesh

"BB"

Barbados

"BY"

Belarus

"BE"

Belgium

"BZ"

Belize

"BJ"

Benin

"BM"

Bermuda

"BT"

Bhutan

"BO"

Bolivia

"BQ"

Bonaire, Sint Eustatius and Saba

"BA"

Bosnia and Herzegovina

"BW"

Botswana

"BV"

Bouvet Island

"BR"

Brazil

"IO"

British Indian Ocean Territory

"BN"

Brunei

"BG"

Bulgaria

"BF"

Burkina Faso

"BI"

Burundi

"CV"

Cabo Verde

"KH"

Cambodia

"CM"

Cameroon

"CA"

Canada

"KY"

Cayman Islands

"CF"

Central African Republic

"TD"

Chad

"CL"

Chile

"CN"

China

"CX"

Christmas Island

"CC"

Cocos (Keeling) Islands

"CO"

Colombia

"KM"

Comoros

"CG"

Congo

"CD"

Congo (the Democratic Republic of the)

"CK"

Cook Islands

"CR"

Costa Rica

"CI"

Côte d'Ivoire

"HR"

Croatia

"CU"

Cuba

"CW"

Curaçao

"CY"

Cyprus

"CZ"

Czech Republic

"DK"

Denmark

"DJ"

Djibouti

"DM"

Dominica

"DO"

Dominican Republic

"EC"

Ecuador

"EG"

Egypt

"SV"

El Salvador

"GQ"

Equatorial Guinea

"ER"

Eritrea

"EE"

Estonia

"ET"

Ethiopia

"FK"

Falkland Islands [Malvinas]

"FO"

Faroe Islands

"FJ"

Fiji

"FI"

Finland

"FR"

France

"GF"

French Guiana

"PF"

French Polynesia

"TF"

French Southern Territories

"GA"

Gabon

"GM"

Gambia

"GE"

Georgia

"DE"

Germany

"GH"

Ghana

"GI"

Gibraltar

"GR"

Greece

"GL"

Greenland

"GD"

Grenada

"GP"

Guadeloupe

"GU"

Guam

"GT"

Guatemala

"GG"

Guernsey

"GN"

Guinea

"GW"

Guinea-Bissau

"GY"

Guyana

"HT"

Haiti

"HM"

Heard Island and McDonald Islands

"VA"

Holy See

"HN"

Honduras

"HK"

Hong Kong

"HU"

Hungary

"IS"

Iceland

"IN"

India

"ID"

Indonesia

"IR"

Iran

"IQ"

Iraq

"IE"

Ireland

"IM"

Isle of Man

"IL"

Israel

"IT"

Italy

"JM"

Jamaica

"JP"

Japan

"JE"

Jersey

"JO"

Jordan

"KZ"
Kazakhstan

"KE"
Kenya

"KI"
Kiribati

"KW"
Kuwait

"KG"
Kyrgyzstan

"LA"
Laos

"LV"
Latvia

"LB"
Lebanon

"LS"
Lesotho

"LR"
Liberia

"LY"
Libya

"LI"
Liechtenstein

"LT"
Lithuania

"LU"
Luxembourg

"MO"
Macao

"MK"
Macedonia

"MG"
Madagascar

"MW"
Malawi

"MY"
Malaysia

"MV"
Maldives

"ML"
Mali

"MT"
Malta

"MH"
Marshall Islands

"MQ"
Martinique

"MR"
Mauritania

"MU"

Mauritius

"YT"

Mayotte

"MX"

Mexico

"FM"

Micronesia (Federated States of)

"MD"

Moldova

"MC"

Monaco

"MN"

Mongolia

"ME"

Montenegro

"MS"

Montserrat

"MA"

Morocco

"MZ"

Mozambique

"MM"

Myanmar

"NA"

Namibia

"NR"

Nauru

"NP"

Nepal

"NL"

Netherlands

"NC"

New Caledonia

"NZ"

New Zealand

"NI"

Nicaragua

"NE"

Niger

"NG"

Nigeria

"NU"

Niue

"NF"

Norfolk Island

"KP"

North Korea

"MP"

Northern Mariana Islands

"NO"

Norway

"OM"

Oman

"PK"

Pakistan

"PW"

Palau

"PS"

Palestine, State of

"PA"

Panama

"PG"

Papua New Guinea

"PY"

Paraguay

"PE"

Peru

"PH"

Philippines

"PN"

Pitcairn

"PL"

Poland

"PT"

Portugal

"PR"

Puerto Rico

"QA"

Qatar

"RE"

Réunion

"RO"

Romania

"RU"

Russia

"RW"

Rwanda

"BL"

Saint Barthélemy

"SH"

Saint Helena, Ascension and Tristan da Cunha

"KN"

Saint Kitts and Nevis

"LC"

Saint Lucia

"MF"

Saint Martin (French part)

"PM"

Saint Pierre and Miquelon

"VC"

Saint Vincent and the Grenadines

"WS"

Samoa

"SM"

San Marino

"ST"

Sao Tome and Principe

"SA"

Saudi Arabia

"SN"

Senegal

"RS"

Serbia

"SC"

Seychelles

"SL"

Sierra Leone

"SG"

Singapore

"SX"

Sint Maarten (Dutch part)

"SK"

Slovakia

"SI"

Slovenia

"SB"

Solomon Islands

"SO"

Somalia

"ZA"

South Africa

"GS"

South Georgia and the South Sandwich Islands

"KR"

South Korea

"SS"

South Sudan

"ES"

Spain

"LK"

Sri Lanka

"SD"

Sudan

"SR"

Suriname

"SJ"

Svalbard and Jan Mayen

"SZ"

Swaziland

"SE"

Sweden

"CH"

Switzerland

"SY"

Syria

"TW"

Taiwan

"TJ"

Tajikistan

"TZ"

Tanzania

"TH"

Thailand

"TL"

Timor-Leste

"TG"

Togo

"TK"

Tokelau

"TO"

Tonga

"TT"

Trinidad and Tobago

"TN"

Tunisia

"TR"

Turkey

"TM"

Turkmenistan

"TC"

Turks and Caicos Islands

"TV"

Tuvalu

"UG"

Uganda

"UA"

Ukraine

"AE"

United Arab Emirates

"GB"

United Kingdom

"UM"

United States Minor Outlying Islands

"US"

United States of America

"UY"

Uruguay

"UZ"

Uzbekistan

"VU"

Vanuatu

"VE"

Venezuela

"VN"

Vietnam

"VG"

Virgin Islands (British)

"VI"

Virgin Islands (U.S.)

"WF"

Wallis and Futuna

"EH"

Western Sahara

"YE"

Yemen

"ZM"

Zambia

"ZW"

Zimbabwe

"p_c_t_final_report": STRING may be null (3.2.6 Does a final report exist?)
"p_c_t_gcp_rules": STRING may be null (3.2.5 Were the clinical tests made according to GCP guidelines)
"p_c_t_period": STRING may be null (3.2.3 period)
"p_c_t_phase": STRING max. 80 characters, may be null (3.2.2 Phase)
"preexisting_clinical_tries": STRING may be null (3.2 Are there already results of clinical trials for the tested drug?)
"registered_in_countries": STRING[] max. 2 characters (3.1 Registration in other states?) - choices:

"AF"

Afghanistan

"AX"

Åland Islands

"AL"

Albania

"DZ"

Algeria

"AS"

American Samoa

"AD"

Andorra

"AO"

Angola

"AI"

Anguilla

"AQ"

Antarctica

"AG"

Antigua and Barbuda

"AR"

Argentina

"AM"

Armenia

"AW"

Aruba

"AU"

Australia

"AT"
  Austria
"AZ"
  Azerbaijan
"BS"
  Bahamas
"BH"
  Bahrain
"BD"
  Bangladesh
"BB"
  Barbados
"BY"
  Belarus
"BE"
  Belgium
"BZ"
  Belize
"BJ"
  Benin
"BM"
  Bermuda
"BT"
  Bhutan
"BO"
  Bolivia
"BQ"
  Bonaire, Sint Eustatius and Saba
"BA"
  Bosnia and Herzegovina
"BW"
  Botswana
"BV"
  Bouvet Island
"BR"
  Brazil
"IO"
  British Indian Ocean Territory
"BN"
  Brunei
"BG"
  Bulgaria
"BF"
  Burkina Faso
"BI"
  Burundi
"CV"
  Cabo Verde
"KH"
  Cambodia
"CM"
  Cameroon

"CA"
Canada

"KY"
Cayman Islands

"CF"
Central African Republic

"TD"
Chad

"CL"
Chile

"CN"
China

"CX"
Christmas Island

"CC"
Cocos (Keeling) Islands

"CO"
Colombia

"KM"
Comoros

"CG"
Congo

"CD"
Congo (the Democratic Republic of the)

"CK"
Cook Islands

"CR"
Costa Rica

"CI"
Côte d'Ivoire

"HR"
Croatia

"CU"
Cuba

"CW"
Curaçao

"CY"
Cyprus

"CZ"
Czech Republic

"DK"
Denmark

"DJ"
Djibouti

"DM"
Dominica

"DO"
Dominican Republic

"EC"
Ecuador

"EG"
Egypt

"SV"
El Salvador
"GQ"
Equatorial Guinea
"ER"
Eritrea
"EE"
Estonia
"ET"
Ethiopia
"FK"
Falkland Islands [Malvinas]
"FO"
Faroe Islands
"FJ"
Fiji
"FI"
Finland
"FR"
France
"GF"
French Guiana
"PF"
French Polynesia
"TF"
French Southern Territories
"GA"
Gabon
"GM"
Gambia
"GE"
Georgia
"DE"
Germany
"GH"
Ghana
"GI"
Gibraltar
"GR"
Greece
"GL"
Greenland
"GD"
Grenada
"GP"
Guadeloupe
"GU"
Guam
"GT"
Guatemala
"GG"
Guernsey

"GN"
  Guinea
"GW"
  Guinea-Bissau
"GY"
  Guyana
"HT"
  Haiti
"HM"
  Heard Island and McDonald Islands
"VA"
  Holy See
"HN"
  Honduras
"HK"
  Hong Kong
"HU"
  Hungary
"IS"
  Iceland
"IN"
  India
"ID"
  Indonesia
"IR"
  Iran
"IQ"
  Iraq
"IE"
  Ireland
"IM"
  Isle of Man
"IL"
  Israel
"IT"
  Italy
"JM"
  Jamaica
"JP"
  Japan
"JE"
  Jersey
"JO"
  Jordan
"KZ"
  Kazakhstan
"KE"
  Kenya
"KI"
  Kiribati
"KW"
  Kuwait

"KG"
Kyrgyzstan
"LA"
Laos
"LV"
Latvia
"LB"
Lebanon
"LS"
Lesotho
"LR"
Liberia
"LY"
Libya
"LI"
Liechtenstein
"LT"
Lithuania
"LU"
Luxembourg
"MO"
Macao
"MK"
Macedonia
"MG"
Madagascar
"MW"
Malawi
"MY"
Malaysia
"MV"
Maldives
"ML"
Mali
"MT"
Malta
"MH"
Marshall Islands
"MQ"
Martinique
"MR"
Mauritania
"MU"
Mauritius
"YT"
Mayotte
"MX"
Mexico
"FM"
Micronesia (Federated States of)
"MD"
Moldova

`"MC"`
    Monaco
`"MN"`
    Mongolia
`"ME"`
    Montenegro
`"MS"`
    Montserrat
`"MA"`
    Morocco
`"MZ"`
    Mozambique
`"MM"`
    Myanmar
`"NA"`
    Namibia
`"NR"`
    Nauru
`"NP"`
    Nepal
`"NL"`
    Netherlands
`"NC"`
    New Caledonia
`"NZ"`
    New Zealand
`"NI"`
    Nicaragua
`"NE"`
    Niger
`"NG"`
    Nigeria
`"NU"`
    Niue
`"NF"`
    Norfolk Island
`"KP"`
    North Korea
`"MP"`
    Northern Mariana Islands
`"NO"`
    Norway
`"OM"`
    Oman
`"PK"`
    Pakistan
`"PW"`
    Palau
`"PS"`
    Palestine, State of
`"PA"`
    Panama

"PG"
Papua New Guinea
"PY"
Paraguay
"PE"
Peru
"PH"
Philippines
"PN"
Pitcairn
"PL"
Poland
"PT"
Portugal
"PR"
Puerto Rico
"QA"
Qatar
"RE"
Réunion
"RO"
Romania
"RU"
Russia
"RW"
Rwanda
"BL"
Saint Barthélemy
"SH"
Saint Helena, Ascension and Tristan da Cunha
"KN"
Saint Kitts and Nevis
"LC"
Saint Lucia
"MF"
Saint Martin (French part)
"PM"
Saint Pierre and Miquelon
"VC"
Saint Vincent and the Grenadines
"WS"
Samoa
"SM"
San Marino
"ST"
Sao Tome and Principe
"SA"
Saudi Arabia
"SN"
Senegal
"RS"
Serbia

"SC"

Seychelles

"SL"

Sierra Leone

"SG"

Singapore

"SX"

Sint Maarten (Dutch part)

"SK"

Slovakia

"SI"

Slovenia

"SB"

Solomon Islands

"SO"

Somalia

"ZA"

South Africa

"GS"

South Georgia and the South Sandwich Islands

"KR"

South Korea

"SS"

South Sudan

"ES"

Spain

"LK"

Sri Lanka

"SD"

Sudan

"SR"

Suriname

"SJ"

Svalbard and Jan Mayen

"SZ"

Swaziland

"SE"

Sweden

"CH"

Switzerland

"SY"

Syria

"TW"

Taiwan

"TJ"

Tajikistan

"TZ"

Tanzania

"TH"

Thailand

"TL"

Timor-Leste

"TG"
　　Togo
"TK"
　　Tokelau
"T0"
　　Tonga
"TT"
　　Trinidad and Tobago
"TN"
　　Tunisia
"TR"
　　Turkey
"TM"
　　Turkmenistan
"TC"
　　Turks and Caicos Islands
"TV"
　　Tuvalu
"UG"
　　Uganda
"UA"
　　Ukraine
"AE"
　　United Arab Emirates
"GB"
　　United Kingdom
"UM"
　　United States Minor Outlying Islands
"US"
　　United States of America
"UY"
　　Uruguay
"UZ"
　　Uzbekistan
"VU"
　　Vanuatu
"VE"
　　Venezuela
"VN"
　　Vietnam
"VG"
　　Virgin Islands (British)
"VI"
　　Virgin Islands (U.S.)
"WF"
　　Wallis and Futuna
"EH"
　　Western Sahara
"YE"
　　Yemen
"ZM"
　　Zambia

```
            "ZW"
                    Zimbabwe

        }
}
```