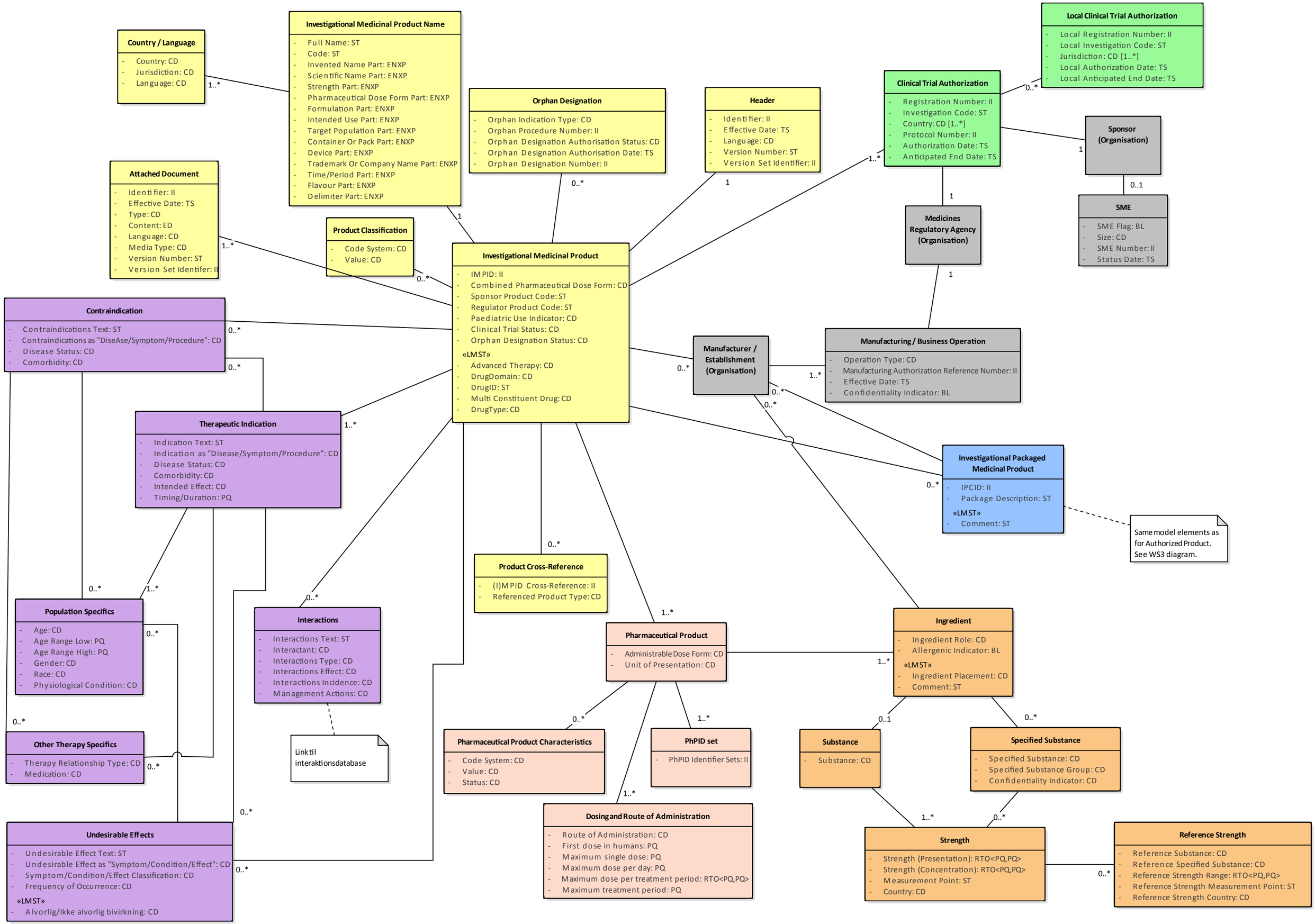
Country / Language
- Country: CD
- Jurisdiction: CD
- Language: CD
Investigational Medicinal Product Name
- Full Name: ST
- Code: ST
- Invented Name Part: ENXP
- Scientific Name Part: ENXP
- Strength Part: ENXP
- Pharmaceutical Dose Form Part: ENXP
- Formulation Part: ENXP
- Intended Use Part: ENXP
- Target Population Part: ENXP
- Container Or Pack Part: ENXP
- Device Part: ENXP
- Trademark Or Company Name Part: ENXP
- Time/Period Part: ENXP
- Flavour Part: ENXP
- Delimiter Part: ENXP
Orphan Designation
- Orphan Indication Type: CD
- Orphan Procedure Number: II
- Orphan Designation Authorisation Status: CD
- Orphan Designation Authorisation Date: TS
- Orphan Designation Number: II
Header
- Identifier: II
- Effective Date: TS
- Language: CD
- Version Number: ST
- Version Set Identifier: II
Local Clinical Trial Authorization
- Local Registration Number: II
- Local Investigation Code: ST
- Jurisdiction: CD [1..*]
- Local Authorization Date: TS
- Local Anticipated End Date: TS
Clinical Trial Authorization
- Registration Number: II
- Investigation Code: ST
- Country: CD [1..*]
- Protocol Number: II
- Authorization Date: TS
- Anticipated End Date: TS
Sponsor (Organisation)
SME
- SME Flag: BL
- Size: CD
- SME Number: II
- Status Date: TS
Attached Document
- Identifier: II
- Effective Date: TS
- Type: CD
- Content: ED
- Language: CD
- Media Type: CD
- Version Number: ST
- Version Set Identifer: II
Product Classification
- Code System: CD
- Value: CD
Investigational Medicinal Product
- IMPID: II
- Combined Pharmaceutical Dose Form: CD
- Sponsor Product Code: ST
- Regulator Product Code: ST
- Paediatric Use Indicator: CD
- Clinical Trial Status: CD
- Orphan Designation Status: CD
«LMST»
- Advanced Therapy: CD
- DrugDomain: CD
- DrugID: ST
- Multi Constituent Drug: CD
- DrugType: CD
Medicines Regulatory Agency (Organisation)
Contraindication
- Contraindications Text: ST
- Contraindications as "DiseAse/Symptom/Procedure": CD
- Disease Status: CD
- Comorbidity: CD
Manufacturer / Establishment (Organisation)
Manufacturing / Business Operation
- Operation Type: CD
- Manufacturing Authorization Reference Number: II
- Effective Date: TS
- Confidentiality Indicator: BL
Therapeutic Indication
- Indication Text: ST
- Indication as "Disease/Symptom/Procedure": CD
- Disease Status: CD
- Comorbidity: CD
- Intended Effect: CD
- Timing/Duration: PQ
Investigational Packaged Medicinal Product
- IPCID: II
- Package Description: ST
«LMST»
- Comment: ST
Same model elements as for Authorized Product. See WS3 diagram.
Product Cross-Reference
- (I)MPID Cross-Reference: II
- Referenced Product Type: CD
Population Specifics
- Age: CD
- Age Range Low: PQ
- Age Range High: PQ
- Gender: CD
- Race: CD
- Physiological Condition: CD
Interactions
- Interactions Text: ST
- Interactant: CD
- Interactions Type: CD
- Interactions Effect: CD
- Interactions Incidence: CD
- Management Actions: CD
Link til interaktionsdatabase
Pharmaceutical Product
- Administrable Dose Form: CD
- Unit of Presentation: CD
Ingredient
- Ingredient Role: CD
- Allergenic Indicator: BL
«LMST»
- Ingredient Placement: CD
- Comment: ST
Other Therapy Specifics
- Therapy Relationship Type: CD
- Medication: CD
Pharmaceutical Product Characteristics
- Code System: CD
- Value: CD
- Status: CD
PhPID set
- PhPID Identifier Sets: II
Substance
- Substance: CD
Specified Substance
- Specified Substance: CD
- Specified Substance Group: CD
- Confidentiality Indicator: CD
Dosing and Route of Administration
- Route of Administration: CD
- First dose in humans: PQ
- Maximum single dose: PQ
- Maximum dose per day: PQ
- Maximum dose per treatment period: RTO<PQ,PQ>
- Maximum treatment period: PQ
Undesirable Effects
- Undesirable Effect Text: ST
- Undesirable Effect as "Symptom/Condition/Effect": CD
- Symptom/Condition/Effect Classification: CD
- Frequency of Occurrence: CD
«LMST»
- Alvorlig/Ikke alvorlig bivirkning: CD
Strength
- Strength (Presentation): RTO<PQ,PQ>
- Strength (Concentration): RTO<PQ,PQ>
- Measurement Point: ST
- Country: CD
Reference Strength
- Reference Substance: CD
- Reference Specified Substance: CD
- Reference Strength Range: RTO<PQ,PQ>
- Reference Strength Measurement Point: ST
- Reference Strength Country: CD