Canadian Clinical Drug Data Set Model

Canadian Clinical Drug Data Set Data Model

The Canadian Clinical Drug Data Set uniquely identifies and accurately describes medicines and a limited number of devices in a standardized format using a set of defining properties. These defining properties are:

- · For the TM concepts: the set of active ingredient substance(s)
- For the NTP concepts: the set of active ingredient substance(s) and their strength(s), the dosage form, and for some products, their unit of
 presentation
- For the MP concepts: the set of active ingredient substance(s) and their strength(s), the dosage form, and for some products, their unit of
 presentation plus the product name and manufacturer company as published in the DPD.

These three types of concepts that make up the Canadian Clinical Drug Data Set can be described in a relational model that associates these medicinal product concepts with their different levels of granularity together. Note that this model may evolve over time to support new use cases (e.g. for immunization).

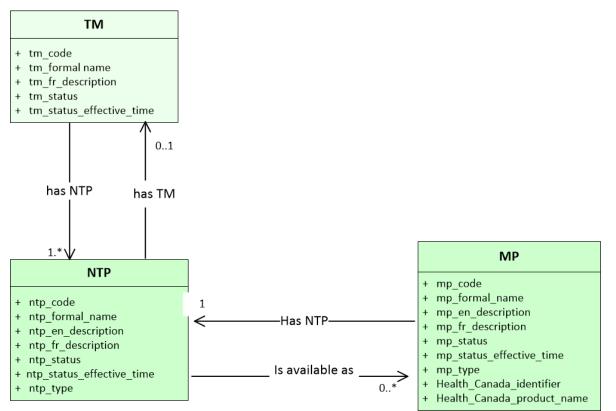


Figure 1: Canadian Clinical Drug Data Set Model

A TM will have one or more NTPs associated with it, but an NTP is not required to be associated to a TM (for example, devices will not be associated with a TM).

A normal NTP has at least one MP associated with it; however, for NTPs with the status of "deprec" (deprecated), there will not be an associated MP. For device NTPs, there are currently no associated MP products. An MP will be associated with one and only one NTP.

Table 1 below provides the definition and an example for each of the core classes in the Canadian Clinical Drug Data Set model.

Table 1: The Canadian Clinical Drug Data Set Model Classes

Model Class	Definition and Description	Example (formal name)
Therapeutic Moiety (TM)	The functional and clinically significant part of the active ingredient substance(s) present in a medicinal product, and as such the TM class is an abstract representation of a medicinal product without reference to strength and dose form, focusing only on active ingredient substance(s).	amlodipine

Non- proprietary Therapeutic Product (NTP)	A brand independent and clinically oriented representation of a manufactured (therapeutic) product. An NTP is described by the set of active ingredient substance(s) (both precise active ingredient substance and basis of strength substance, if different) and their strength(s), the dosage form, and for some products, their unit of presentation	amlodipine (amlodipine besylate) 2.5 mg oral tablet
Manufacture d Product (MP)	A brand specific drug that is or, within the lifetime of the CCDD, has been available for prescribing and dispensing in Canada.	ACT AMLODIPINE (amlodipine (amlodipine besylate) 2.5 mg oral tablets) ACTAVIS PHARMA COMPANY

Technical Specification

The detailed technical specification for the content of the Canadian Clinical Drug Data Set which defines the attributes used for each class is provided in a separate Technical Specification Technical Specification document.