Annotation Acquisition Model for PharmML and Non-PharmML Models in DDMoRe Implemented version: 1.3.0

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Section 1: Bookkeeping.

Code: eur:5-9-section-one
Subsection of: eur:5-9-eur with position: 1.
PharmML slot: NA.
Non-PharmML slot: NA.
Allows freetext alternative: false.

Section 1.1: Corresponding Author or Submitter (one Account).

Code: eur:5-9-section-one-one
Subsection of: eur:5-9-section-one with position: 1.
PharmML slot: wat:model-has-correspondent.
Non-PharmML slot: wat:model-has-correspondent.
Allows freetext alternative: false.

Section 1.1: Discrepancy between implemented model and original publication.

Code: eur:5-9-section-one-ten
Subsection of: eur:5-9-section-one with position: 10.
PharmML slot: wat:model-implementation-source-discrepancies-freetext.
Non-PharmML slot: wat:model-implementation-source-discrepancies-freetext.
Allows freetext alternative: false.

Section 1.2: Publication identification.

Code: eur:5-9-section-one-two
Subsection of: eur:5-9-section-one with position: 2.

28 PharmML slot: ps:model-has-publication-source-external-id.
29 Non-PharmML slot: ps:model-has-publication-source-external-id.
30 Allows freetext alternative: false.

31 Section 1.3: Model Name.

32 Code: eur:5-9-section-one-three
33 Subsection of: eur:5-9-section-one with position: 3.
34 PharmML slot: ps:model-has-name.
35 Non-PharmML slot: ps:model-has-name.
36 Allows freetext alternative: false.

37 Section 1.4: Model authors and affiliation.

38 Code: eur:5-9-section-one-four
39 Subsection of: eur:5-9-section-one with position: 4.
40 PharmML slot: ps:model-has-author.
41 Non-PharmML slot: ps:model-has-author.
42 Allows freetext alternative: false.

43 Section 1.5: Modelling context description.

44 Code: eur:5-9-section-one-five
45 Subsection of: eur:5-9-section-one with position: 5.
46 PharmML slot: ps:model-has-description.
47 Non-PharmML slot: ps:model-has-description.
48 Allows freetext alternative: false.

49 Section 1.6: Short description of the final model.

50 Code: eur:5-9-section-one-six
51 Subsection of: eur:5-9-section-one with position: 6.
52 PharmML slot: ps:model-has-description-short.
53 Non-PharmML slot: ps:model-has-description-short.
54 Allows freetext alternative: false.

55 Section 1.7: Long technical model description.

56 Code: eur:5-9-section-one-seven
57 Subsection of: eur:5-9-section-one with position: 7.
58 PharmML slot: ps:model-has-description-long.
59 Non-PharmML slot: ps:model-has-description-long.
60 Allows freetext alternative: false.

Section 1.8: Model implementation requiring submitter?s additional knowledge.

Code: eur:5-9-section-one-eight
Subsection of: eur:5-9-section-one with position: 8.
PharmML slot: wat:model-origin-of-code-in-literature-controlled.
Non-PharmML slot: wat:model-origin-of-code-in-literature-controlled.
Allows freetext alternative: false.

Section 1.9: Model compliance with original publication.

Code: eur:5-9-section-one-nine
Subsection of: eur:5-9-section-one with position: 9.
PharmML slot: wat:model-implementation-conforms-to-literature-controlled.
Non-PharmML slot: wat:model-implementation-conforms-to-literature-controlled.
Allows freetext alternative: false.

Section 2: Context of use.

Code: eur:5-9-section-two
Subsection of: eur:5-9-eur with position: 2.
PharmML slot: NA.
Non-PharmML slot: NA.
Allows freetext alternative: false.

Section 2.1: Context of model development.

Code: eur:5-9-section-two-one
Subsection of: eur:5-9-section-two with position: 1.
PharmML slot: ps:model-modelling-question.
Non-PharmML slot: ps:model-modelling-question.
Allows freetext alternative: false.

Section 2.2: Nature of research.

Code: eur:5-9-section-two-two
Subsection of: eur:5-9-section-two with position: 2.
PharmML slot: ps:model-research-stage.
Non-PharmML slot: ps:model-research-stage.
Allows freetext alternative: false.

₉₂ Section 2.3: Therapeutic/disease area.

- ₉₃ <u>Code:</u> eur:5-9-section-two-three
- ₉₄ <u>Subsection of:</u> eur:5-9-section-two with position: 3.
- ₉₅ <u>PharmML slot:</u> ps:model-field-purpose.
- ₉₆ <u>Non-PharmML slot:</u> ps:model-field-purpose.
- ₉₇ <u>Allows freetext alternative:</u> false.

₉₈ Section 2.4: Disease/Indications.

- ₉₉ <u>Code:</u> eur:5-9-section-two-four
- ₁₀₀ <u>Subsection of:</u> eur:5-9-section-two with position: 4.
- ₁₀₁ <u>PharmML slot:</u> ps:model-related-to-disease-or-condition.
- ₁₀₂ <u>Non-PharmML slot:</u> ps:model-related-to-disease-or-condition.
- ₁₀₃ <u>Allows freetext alternative:</u> false.

₁₀₄ Section 2.5: Modelling task in scope.

- ₁₀₅ <u>Code:</u> eur:5-9-section-two-five
- ₁₀₆ <u>Subsection of:</u> eur:5-9-section-two with position: 5.
- ₁₀₇ <u>PharmML slot:</u> ps:model-tasks-in-scope.
- ₁₀₈ <u>Non-PharmML slot:</u> ps:model-tasks-in-scope.
- ₁₀₉ <u>Allows freetext alternative:</u> false.

₁₁₀ Section 3: Design and Data.

- ₁₁₁ <u>Code:</u> eur:5-9-section-three
- ₁₁₂ <u>Subsection of:</u> eur:5-9-eur with position: 3.
- ₁₁₃ <u>PharmML slot:</u> NA.
- ₁₁₄ <u>Non-PharmML slot:</u> NA.
- ₁₁₅ <u>Allows freetext alternative:</u> false.

₁₁₆ Section 3.1: Design overview.

- ₁₁₇ <u>Code:</u> eur:5-9-section-three-one
- ₁₁₈ <u>Subsection of:</u> eur:5-9-section-three with position: 1.
- ₁₁₉ <u>PharmML slot:</u> NA.
- ₁₂₀ <u>Non-PharmML slot:</u> NA.
- ₁₂₁ <u>Allows freetext alternative:</u> false.

Section 3.1.3: Type(s) of data.

122

123 <u>Code:</u> eur:5-9-section-three-one-three

124 <u>Subsection of:</u> eur:5-9-section-three-one with position: 3.

125 <u>PharmML slot:</u> ps:trialdesign-HasAssociatedDataOfType-DataPool.

126 <u>Non-PharmML slot:</u> ps:model-HasAssociatedDataOfType-DataPool.

127 <u>Allows freetext alternative:</u> false.

Section 3.1.4: Species.

128

129 <u>Code:</u> eur:5-9-section-three-one-four

130 <u>Subsection of:</u> eur:5-9-section-three-one with position: 4.

131 <u>PharmML slot:</u> NA.

132 <u>Non-PharmML slot:</u> NA.

133 <u>Allows freetext alternative:</u> false.

Section 3.1.4.1: Animals.

134

135 <u>Code:</u> eur:5-9-section-three-one-four-one

136 <u>Subsection of:</u> eur:5-9-section-three-one-four with position: 1.

137 <u>PharmML slot:</u> ps:trialdesign-HasAssociatedOrganismType-DataPool.

138 <u>Non-PharmML slot:</u> ps:model-HasAssociatedOrganismType-DataPool.

139 <u>Allows freetext alternative:</u> true.

Section 3.1.4.2: Humans.

140

141 <u>Code:</u> eur:5-9-section-three-one-four-two

142 <u>Subsection of:</u> eur:5-9-section-three-one-four with position: 2.

143 <u>PharmML slot:</u> ps:trialdesign-HasAssociatedHumanGroupByMedicalStatus-DataPool.

144 <u>Non-PharmML slot:</u> ps:model-HasAssociatedHumanGroupByMedicalStatus-DataPool.

145 <u>Allows freetext alternative:</u> false.

Section 3.2: Studied Drug(s).

146

147 <u>Code:</u> eur:5-9-section-three-two

148 <u>Subsection of:</u> eur:5-9-section-three with position: 2.

149 <u>PharmML slot:</u> NA.

150 <u>Non-PharmML slot:</u> NA.

151 <u>Allows freetext alternative:</u> false.

Section 3.2.1: Name(s).

152

153 Code: eur:5-9-section-three-two-one

154 Subsection of: eur:5-9-section-three-two with position: 1.

155 PharmML slot: NA.

156 Non-PharmML slot: NA.

157 Allows freetext alternative: false.

Section 3.2.1.1: Studied type.

158

159 Code: eur:5-9-section-three-two-one-one

160 Subsection of: eur:5-9-section-three-two-one with position: 1.

161 PharmML slot: ps:trialdesign-HasStudiedSubstanceAtttibute.

162 Non-PharmML slot: ps:model-HasStudiedSubstanceAttribute.

163 Allows freetext alternative: false.

Section 3.2.1.2: Chebi ID.

164

165 Code: eur:5-9-section-three-two-one-two

166 Subsection of: eur:5-9-section-three-two-one with position: 2.

167 PharmML slot: NA.

168 Non-PharmML slot: NA.

169 Allows freetext alternative: false.

Section 3.2.1.2: Drug 1.

170

171 Code: eur:5-9-section-three-two-one-two

172 Subsection of: eur:5-9-section-three-two-one with position: 2.

173 PharmML slot: NA.

174 Non-PharmML slot: NA.

175 Allows freetext alternative: false.

Section 3.2.1.2.1: Name of drug 1.

176

177 Code: eur:5-9-section-three-two-one-two-one

178 Subsection of: eur:5-9-section-three-two-one-two with position: 3.

179 PharmML slot: ps:model-NameOfDrug1-freetext.

180 Non-PharmML slot: ps:model-NameOfDrug1-freetext.

181 Allows freetext alternative: false.

Section 3.2.1.2.2: Chebi ID of drug 1.

182

183 Code: eur:5-9-section-three-two-one-two-two
184 Subsection of: eur:5-9-section-three-two-one-two with position: 2.
185 PharmML slot: ps:model-ChebiIdOfDrug1.
186 Non-PharmML slot: ps:model-ChebiIdOfDrug1.
187 Allows freetext alternative: false.

Section 3.2.1.2.3: DrugBank ID of drug 1.

188

189 Code: eur:5-9-section-three-two-one-two-three
190 Subsection of: eur:5-9-section-three-two-one-two with position: 2.
191 PharmML slot: ps:model-DrugBankIdOfDrug1.
192 Non-PharmML slot: ps:model-DrugBankIdOfDrug1.
193 Allows freetext alternative: false.

Section 3.2.1.2.4: Type of drug (s) or stimulus for drug 1.

194

195 Code: eur:5-9-section-three-two-one-two-four
196 Subsection of: eur:5-9-section-three-two-one-two with position: 4.
197 PharmML slot: ps:model-TypeOfDrug1.
198 Non-PharmML slot: ps:model-TypeOfDrug1.
199 Allows freetext alternative: false.

Section 3.2.1.2.4: Dose amount min of drug 1.

200

201 Code: eur:5-9-section-three-two-one-two-four
202 Subsection of: eur:5-9-section-three-two-one-two with position: 4.
203 PharmML slot: ps:model-hasDoseAmountMin-Drug1.
204 Non-PharmML slot: ps:model-hasDoseAmountMin-Drug1.
205 Allows freetext alternative: false.

Section 3.2.1.2.5: Dose amount max of drug 1.

206

207 Code: eur:5-9-section-three-two-one-two-five
208 Subsection of: eur:5-9-section-three-two-one-two with position: 5.
209 PharmML slot: ps:model-hasDoseAmountMax-Drug1.
210 Non-PharmML slot: ps:model-hasDoseAmountMax-Drug1.
211 Allows freetext alternative: false.

212 Section 3.2.1.2.6: Dose amount unit of drug 1.

213   Code: eur:5-9-section-three-two-one-two-six
214   Subsection of: eur:5-9-section-three-two-one-two with position: 6.
215   PharmML slot: ps:model-hasDoseAmountUnit-Drug1.
216   Non-PharmML slot: ps:model-hasDoseAmountUnit-Drug1.
217   Allows freetext alternative: false.

218 Section 3.2.1.3: DrugBank ID.

219   Code: eur:5-9-section-three-two-one-three
220   Subsection of: eur:5-9-section-three-two-one with position: 3.
221   PharmML slot: NA.
222   Non-PharmML slot: NA.
223   Allows freetext alternative: false.

224 Section 3.2.1.3: Drug 2.

225   Code: eur:5-9-section-three-two-one-three
226   Subsection of: eur:5-9-section-three-two-one with position: 3.
227   PharmML slot: NA.
228   Non-PharmML slot: NA.
229   Allows freetext alternative: false.

230 Section 3.2.1.3.1: Name of drug 2.

231   Code: eur:5-9-section-three-two-one-three-one
232   Subsection of: eur:5-9-section-three-two-one-two with position: 3.
233   PharmML slot: ps:model-NameOfDrug2-freetext.
234   Non-PharmML slot: ps:model-NameOfDrug2-freetext.
235   Allows freetext alternative: false.

236 Section 3.2.1.3.2: Chebi ID of drug 2.

237   Code: eur:5-9-section-three-two-one-three-two
238   Subsection of: eur:5-9-section-three-two-one-two with position: 2.
239   PharmML slot: ps:model-ChebiIdOfDrug2.
240   Non-PharmML slot: ps:model-ChebiIdOfDrug2.
241   Allows freetext alternative: false.

Section 3.2.1.3.3: DrugBank ID of drug 2.

242

243 Code: eur:5-9-section-three-two-one-three-three
244 Subsection of: eur:5-9-section-three-two-one-two with position: 2.
245 PharmML slot: ps:model-DrugBankIdOfDrug2.
246 Non-PharmML slot: ps:model-DrugBankIdOfDrug2.
247 Allows freetext alternative: false.

Section 3.2.1.3.4: Type of drug (s) or stimulus for drug 2.

248

249 Code: eur:5-9-section-three-two-one-three-four
250 Subsection of: eur:5-9-section-three-two-one-two with position: 4.
251 PharmML slot: ps:model-TypeOfDrug2.
252 Non-PharmML slot: ps:model-TypeOfDrug2.
253 Allows freetext alternative: false.

Section 3.2.1.3.4: Dose amount min of drug 2.

254

255 Code: eur:5-9-section-three-two-one-three-four
256 Subsection of: eur:5-9-section-three-two-one-three with position: 4.
257 PharmML slot: ps:model-hasDoseAmountMin-Drug2.
258 Non-PharmML slot: ps:model-hasDoseAmountMin-Drug2.
259 Allows freetext alternative: false.

Section 3.2.1.3.5: Dose amount max of drug 2.

260

261 Code: eur:5-9-section-three-two-one-three-five
262 Subsection of: eur:5-9-section-three-two-one-three with position: 5.
263 PharmML slot: ps:model-hasDoseAmountMax-Drug2.
264 Non-PharmML slot: ps:model-hasDoseAmountMax-Drug2.
265 Allows freetext alternative: false.

Section 3.2.1.3.6: Dose amount unit of drug 2.

266

267 Code: eur:5-9-section-three-two-one-three-six
268 Subsection of: eur:5-9-section-three-two-one-three with position: 6.
269 PharmML slot: ps:model-hasDoseAmountUnit-Drug2.
270 Non-PharmML slot: ps:model-hasDoseAmountUnit-Drug2.
271 Allows freetext alternative: false.

Section 3.2.1.4: Other.

272

273 Code: eur:5-9-section-three-two-one-four

274 Subsection of: eur:5-9-section-three-two-one with position: 4.

275 PharmML slot: NA.

276 Non-PharmML slot: NA.

277 Allows freetext alternative: false.

Section 3.2.1.4: Drug 3.

278

279 Code: eur:5-9-section-three-two-one-four

280 Subsection of: eur:5-9-section-three-two-one with position: 4.

281 PharmML slot: NA.

282 Non-PharmML slot: NA.

283 Allows freetext alternative: false.

Section 3.2.1.4.1: Name of drug 3.

284

285 Code: eur:5-9-section-three-two-one-four-one

286 Subsection of: eur:5-9-section-three-two-one-two with position: 3.

287 PharmML slot: ps:model-NameOfDrug3-freetext.

288 Non-PharmML slot: ps:model-NameOfDrug3-freetext.

289 Allows freetext alternative: false.

Section 3.2.1.4.2: Chebi ID of drug 3.

290

291 Code: eur:5-9-section-three-two-one-four-two

292 Subsection of: eur:5-9-section-three-two-one-two with position: 2.

293 PharmML slot: ps:model-ChebiIdOfDrug3.

294 Non-PharmML slot: ps:model-ChebiIdOfDrug3.

295 Allows freetext alternative: false.

Section 3.2.1.4.3: DrugBank ID of drug 3.

296

297 Code: eur:5-9-section-three-two-one-four-three

298 Subsection of: eur:5-9-section-three-two-one-two with position: 2.

299 PharmML slot: ps:model-DrugBankIdOfDrug3.

300 Non-PharmML slot: ps:model-DrugBankIdOfDrug3.

301 Allows freetext alternative: false.

302 Section 3.2.1.4.4: Type of drug (s) or stimulus for drug 3.

303   Code: eur:5-9-section-three-two-one-four-four
304   Subsection of: eur:5-9-section-three-two-one-two with position: 4.
305   PharmML slot: ps:model-TypeOfDrug3.
306   Non-PharmML slot: ps:model-TypeOfDrug3.
307   Allows freetext alternative: false.

308 Section 3.2.1.4.4: Dose amount min of drug 3.

309   Code: eur:5-9-section-three-two-one-four-four
310   Subsection of: eur:5-9-section-three-two-one-four with position: 4.
311   PharmML slot: ps:model-hasDoseAmountMin-Drug3.
312   Non-PharmML slot: ps:model-hasDoseAmountMin-Drug3.
313   Allows freetext alternative: false.

314 Section 3.2.1.4.5: Dose amount max of drug 3.

315   Code: eur:5-9-section-three-two-one-four-five
316   Subsection of: eur:5-9-section-three-two-one-four with position: 5.
317   PharmML slot: ps:model-hasDoseAmountMax-Drug3.
318   Non-PharmML slot: ps:model-hasDoseAmountMax-Drug3.
319   Allows freetext alternative: false.

320 Section 3.2.1.4.6: Dose amount unit of drug 3.

321   Code: eur:5-9-section-three-two-one-four-six
322   Subsection of: eur:5-9-section-three-two-one-four with position: 6.
323   PharmML slot: ps:model-hasDoseAmountUnit-Drug3.
324   Non-PharmML slot: ps:model-hasDoseAmountUnit-Drug3.
325   Allows freetext alternative: false.

326 Section 3.2.1.5: Drug 4.

327   Code: eur:5-9-section-three-two-one-five
328   Subsection of: eur:5-9-section-three-two-one with position: 2.
329   PharmML slot: NA.
330   Non-PharmML slot: NA.
331   Allows freetext alternative: false.

332 Section 3.2.1.5.1: Name of drug 4.

333   Code: eur:5-9-section-three-two-one-five-one
334   Subsection of: eur:5-9-section-three-two-one-two with position: 3.
335   PharmML slot: ps:model-NameOfDrug4-freetext.
336   Non-PharmML slot: ps:model-NameOfDrug4-freetext.
337   Allows freetext alternative: false.

338 Section 3.2.1.5.2: Chebi ID of drug 4.

339   Code: eur:5-9-section-three-two-one-five-two
340   Subsection of: eur:5-9-section-three-two-one-two with position: 2.
341   PharmML slot: ps:model-ChebiIdOfDrug4.
342   Non-PharmML slot: ps:model-ChebiIdOfDrug4.
343   Allows freetext alternative: false.

344 Section 3.2.1.5.3: DrugBank ID of drug 4.

345   Code: eur:5-9-section-three-two-one-five-three
346   Subsection of: eur:5-9-section-three-two-one-two with position: 2.
347   PharmML slot: ps:model-DrugBankIdOfDrug4.
348   Non-PharmML slot: ps:model-DrugBankIdOfDrug4.
349   Allows freetext alternative: false.

350 Section 3.2.1.5.4: Type of drug (s) or stimulus for drug 4.

351   Code: eur:5-9-section-three-two-one-five-four
352   Subsection of: eur:5-9-section-three-two-one-two with position: 4.
353   PharmML slot: ps:model-TypeOfDrug4.
354   Non-PharmML slot: ps:model-TypeOfDrug4.
355   Allows freetext alternative: false.

356 Section 3.2.1.5.4: Dose amount min of drug 4.

357   Code: eur:5-9-section-three-two-one-five-four
358   Subsection of: eur:5-9-section-three-two-one-five with position: 4.
359   PharmML slot: ps:model-hasDoseAmountMin-Drug4.
360   Non-PharmML slot: ps:model-hasDoseAmountMin-Drug4.
361   Allows freetext alternative: false.

Section 3.2.1.5.5: Dose amount max of drug 4.

363 Code: eur:5-9-section-three-two-one-five-five
364 Subsection of: eur:5-9-section-three-two-one-five with position: 5.
365 PharmML slot: ps:model-hasDoseAmountMax-Drug4.
366 Non-PharmML slot: ps:model-hasDoseAmountMax-Drug4.
367 Allows freetext alternative: false.

Section 3.2.1.5.6: Dose amount unit of drug 4.

369 Code: eur:5-9-section-three-two-one-five-six
370 Subsection of: eur:5-9-section-three-two-one-five with position: 6.
371 PharmML slot: ps:model-hasDoseAmountUnit-Drug4.
372 Non-PharmML slot: ps:model-hasDoseAmountUnit-Drug4.
373 Allows freetext alternative: false.

Section 3.2.1.6: Drug 5.

375 Code: eur:5-9-section-three-two-one-six
376 Subsection of: eur:5-9-section-three-two-one with position: 2.
377 PharmML slot: NA.
378 Non-PharmML slot: NA.
379 Allows freetext alternative: false.

Section 3.2.1.6.1: Name of drug 5.

381 Code: eur:5-9-section-three-two-one-six-one
382 Subsection of: eur:5-9-section-three-two-one-two with position: 3.
383 PharmML slot: ps:model-NameOfDrug5-freetext.
384 Non-PharmML slot: ps:model-NameOfDrug5-freetext.
385 Allows freetext alternative: false.

Section 3.2.1.6.2: Chebi ID of drug 5.

387 Code: eur:5-9-section-three-two-one-six-two
388 Subsection of: eur:5-9-section-three-two-one-two with position: 2.
389 PharmML slot: ps:model-ChebiIdOfDrug5.
390 Non-PharmML slot: ps:model-ChebiIdOfDrug5.
391 Allows freetext alternative: false.

Section 3.2.1.6.3: DrugBank ID of drug 5.

Code: eur:5-9-section-three-two-one-six-three

Subsection of: eur:5-9-section-three-two-one-two with position: 2.

PharmML slot: ps:model-DrugBankIdOfDrug5.

Non-PharmML slot: ps:model-DrugBankIdOfDrug5.

Allows freetext alternative: false.

Section 3.2.1.6.4: Type of drug (s) or stimulus for drug 5.

Code: eur:5-9-section-three-two-one-six-four

Subsection of: eur:5-9-section-three-two-one-two with position: 4.

PharmML slot: ps:model-TypeOfDrug5.

Non-PharmML slot: ps:model-TypeOfDrug5.

Allows freetext alternative: false.

Section 3.2.1.6.4: Dose amount min of drug 5.

Code: eur:5-9-section-three-two-one-six-four

Subsection of: eur:5-9-section-three-two-one-six with position: 4.

PharmML slot: ps:model-hasDoseAmountMin-Drug5.

Non-PharmML slot: ps:model-hasDoseAmountMin-Drug5.

Allows freetext alternative: false.

Section 3.2.1.6.5: Dose amount max of drug 5.

Code: eur:5-9-section-three-two-one-six-five

Subsection of: eur:5-9-section-three-two-one-six with position: 5.

PharmML slot: ps:model-hasDoseAmountMax-Drug5.

Non-PharmML slot: ps:model-hasDoseAmountMax-Drug5.

Allows freetext alternative: false.

Section 3.2.1.6.6: Dose amount unit of drug 6.

Code: eur:5-9-section-three-two-one-six-six

Subsection of: eur:5-9-section-three-two-one-six with position: 6.

PharmML slot: ps:model-hasDoseAmountUnit-Drug5.

Non-PharmML slot: ps:model-hasDoseAmountUnit-Drug5.

Allows freetext alternative: false.

Section 3.2.2: Type of drug (s) or stimulus.

Code: eur:5-9-section-three-two-two

Subsection of: eur:5-9-section-three-two with position: 2.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 3.2.3: Route of administration.

Code: eur:5-9-section-three-two-three

Subsection of: eur:5-9-section-three-two with position: 3.

PharmML slot: ps:trialdesign-HasAssociatedRouteOfAdministration-DataPool.

Non-PharmML slot: ps:model-HasAssociatedRouteOfAdministration-DataPool.

Allows freetext alternative: true.

Section 3.2.6: Dose regimen.

Code: eur:5-9-section-three-two-six

Subsection of: eur:5-9-section-three-two with position: 6.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 3.2.6.1: Dose regimen.

Code: eur:5-9-section-three-two-six-one

Subsection of: eur:5-9-section-three-two-six with position: 1.

PharmML slot: ps:trialdesign-HasAssociatedDoseRegimen-DataPool.

Non-PharmML slot: ps:model-HasAssociatedDoseRegimen-DataPool.

Allows freetext alternative: false.

Section 3.2.6.2: Dose amount.

Code: eur:5-9-section-three-two-six-two

Subsection of: eur:5-9-section-three-two-six with position: 2.

PharmML slot: ps:trialdesign-HasAssociatedDoseAmount-DataPool.

Non-PharmML slot: ps:model-HasAssociatedDoseAmount-DataPool.

Allows freetext alternative: false.

Section 3.2.6.3: Frequency.

Code: eur:5-9-section-three-two-six-three

Subsection of: eur:5-9-section-three-two-six with position: 3.

PharmML slot: ps:trialdesign-HasAssociatedDoseFrequency-DataPool.

Non-PharmML slot: ps:model-HasAssociatedDoseFrequency-DataPool.

Allows freetext alternative: false.

Section 3.2.7: Dose amount range.

Code: eur:5-9-section-three-two-seven

Subsection of: eur:5-9-section-three-two with position: 7.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 3.2.7.1: min.

Code: eur:5-9-section-three-two-seven-one

Subsection of: eur:5-9-section-three-two-seven with position: 1.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 3.2.7.2: max.

Code: eur:5-9-section-three-two-seven-two

Subsection of: eur:5-9-section-three-two-seven with position: 2.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 3.2.8: Dose amount unit.

Code: eur:5-9-section-three-two-eight

Subsection of: eur:5-9-section-three-two with position: 8.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 3.3: Observed (dependent) variable(s).

482

483 Code: eur:5-9-section-three-three

484 Subsection of: eur:5-9-section-three with position: 3.

485 PharmML slot: NA.

486 Non-PharmML slot: NA.

487 Allows freetext alternative: false.

Section 3.3.1: Listing.

488

489 Code: eur:5-9-section-three-three-one

490 Subsection of: eur:5-9-section-three-three with position: 1.

491 PharmML slot: NA.

492 Non-PharmML slot: NA.

493 Allows freetext alternative: false.

Section 3.3.1: Listing.

494

495 Code: eur:5-9-section-three-three-one

496 Subsection of: eur:5-9-section-three-three with position: 1.

497 PharmML slot: NA.

498 Non-PharmML slot: NA.

499 Allows freetext alternative: false.

Section 3.3.1.1: Observed variable 1.

500

501 Code: eur:5-9-section-three-three-one-one

502 Subsection of: eur:5-9-section-three-three-one with position: 1.

503 PharmML slot: NA.

504 Non-PharmML slot: NA.

505 Allows freetext alternative: false.

Section 3.3.1.1.1: OV1's Link to studied drug(s) or stimulus(i).

506

507 Code: eur:5-9-section-three-three-one-one-one

508 Subsection of: eur:5-9-section-three-three-one-one with position: 1.

509 PharmML slot: ps:model-OVLinksToDrug-OV1.

510 Non-PharmML slot: ps:model-OVLinksToDrug-OV1.

511 Allows freetext alternative: false.

Section 3.3.1.1.2: OV1's nature of the variable.

512

513   Code: eur:5-9-section-three-three-one-one-two

514   Subsection of: eur:5-9-section-three-three-one-one with position: 2.

515   PharmML slot: ps:model-OVHasNature-OV1.

516   Non-PharmML slot: ps:model-OVHasNature-OV1.

517   Allows freetext alternative: false.

Section 3.3.1.1.3: OV1's units.

518

519   Code: eur:5-9-section-three-three-one-one-three

520   Subsection of: eur:5-9-section-three-three-one-one with position: 3.

521   PharmML slot: ps:model-OVHasUnits-OV1.

522   Non-PharmML slot: ps:model-OVHasUnits-OV1.

523   Allows freetext alternative: false.

Section 3.3.1.1.4: OV1's type of matrix.

524

525   Code: eur:5-9-section-three-three-one-one-four

526   Subsection of: eur:5-9-section-three-three-one-one with position: 4.

527   PharmML slot: ps:model-OVHasMatrixType-OV1.

528   Non-PharmML slot: ps:model-OVHasMatrixType-OV1.

529   Allows freetext alternative: false.

Section 3.3.1.1.5: OV1's type of observed variable.

530

531   Code: eur:5-9-section-three-three-one-one-five

532   Subsection of: eur:5-9-section-three-three-one-one with position: 5.

533   PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV1.

534   Non-PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV1.

535   Allows freetext alternative: false.

Section 3.3.1.2: Observed variable 2.

536

537   Code: eur:5-9-section-three-three-one-two

538   Subsection of: eur:5-9-section-three-three-one with position: 2.

539   PharmML slot: NA.

540   Non-PharmML slot: NA.

541   Allows freetext alternative: false.

Section 3.3.1.2.1: OV2's Link to studied drug(s) or stimulus(i).

542

543 Code: eur:5-9-section-three-three-one-two-one

544 Subsection of: eur:5-9-section-three-three-one-two with position: 1.

545 PharmML slot: ps:model-OVLinksToDrug-OV2.

546 Non-PharmML slot: ps:model-OVLinksToDrug-OV2.

547 Allows freetext alternative: false.

Section 3.3.1.2.2: OV2's nature of the variable.

548

549 Code: eur:5-9-section-three-three-one-two-two

550 Subsection of: eur:5-9-section-three-three-one-two with position: 2.

551 PharmML slot: ps:model-OVHasNature-OV2.

552 Non-PharmML slot: ps:model-OVHasNature-OV2.

553 Allows freetext alternative: false.

Section 3.3.1.2.3: OV2's units.

554

555 Code: eur:5-9-section-three-three-one-two-three

556 Subsection of: eur:5-9-section-three-three-one-two with position: 3.

557 PharmML slot: ps:model-OVHasUnits-OV2.

558 Non-PharmML slot: ps:model-OVHasUnits-OV2.

559 Allows freetext alternative: false.

Section 3.3.1.2.4: OV2's type of matrix.

560

561 Code: eur:5-9-section-three-three-one-two-four

562 Subsection of: eur:5-9-section-three-three-one-two with position: 4.

563 PharmML slot: ps:model-OVHasMatrixType-OV2.

564 Non-PharmML slot: ps:model-OVHasMatrixType-OV2.

565 Allows freetext alternative: false.

Section 3.3.1.2.5: OV2's type of observed variable.

566

567 Code: eur:5-9-section-three-three-one-two-five

568 Subsection of: eur:5-9-section-three-three-one-two with position: 5.

569 PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV2.

570 Non-PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV2.

571 Allows freetext alternative: false.

Section 3.3.1.3: Observed variable 3.

572

573 <u>Code:</u> eur:5-9-section-three-three-one-three
574 <u>Subsection of:</u> eur:5-9-section-three-three-one with position: 3.
575 <u>PharmML slot:</u> NA.
576 <u>Non-PharmML slot:</u> NA.
577 <u>Allows freetext alternative:</u> false.

Section 3.3.1.3.1: OV3's Link to studied drug(s) or stimulus(i).

578

579 <u>Code:</u> eur:5-9-section-three-three-one-three-one
580 <u>Subsection of:</u> eur:5-9-section-three-three-one-three with position: 1.
581 <u>PharmML slot:</u> ps:model-OVLinksToDrug-OV3.
582 <u>Non-PharmML slot:</u> ps:model-OVLinksToDrug-OV3.
583 <u>Allows freetext alternative:</u> false.

Section 3.3.1.3.2: OV3's nature of the variable.

584

585 <u>Code:</u> eur:5-9-section-three-three-one-three-two
586 <u>Subsection of:</u> eur:5-9-section-three-three-one-three with position: 2.
587 <u>PharmML slot:</u> ps:model-OVHasNature-OV3.
588 <u>Non-PharmML slot:</u> ps:model-OVHasNature-OV3.
589 <u>Allows freetext alternative:</u> false.

Section 3.3.1.3.3: OV3's units.

590

591 <u>Code:</u> eur:5-9-section-three-three-one-three-three
592 <u>Subsection of:</u> eur:5-9-section-three-three-one-three with position: 3.
593 <u>PharmML slot:</u> ps:model-OVHasUnits-OV3.
594 <u>Non-PharmML slot:</u> ps:model-OVHasUnits-OV3.
595 <u>Allows freetext alternative:</u> false.

Section 3.3.1.3.4: OV3's type of matrix.

596

597 <u>Code:</u> eur:5-9-section-three-three-one-three-four
598 <u>Subsection of:</u> eur:5-9-section-three-three-one-three with position: 4.
599 <u>PharmML slot:</u> ps:model-OVHasMatrixType-OV3.
600 <u>Non-PharmML slot:</u> ps:model-OVHasMatrixType-OV3.
601 <u>Allows freetext alternative:</u> false.

Section 3.3.1.3.5: OV3's type of observed variable.

602

603   Code: eur:5-9-section-three-three-one-three-five

604   Subsection of: eur:5-9-section-three-three-one-three with position: 5.

605   PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV3.

606   Non-PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV3.

607   Allows freetext alternative: false.

Section 3.3.1.4: Observed variable 4.

608

609   Code: eur:5-9-section-three-three-one-four

610   Subsection of: eur:5-9-section-three-three-one with position: 4.

611   PharmML slot: NA.

612   Non-PharmML slot: NA.

613   Allows freetext alternative: false.

Section 3.3.1.4.1: OV4's Link to studied drug(s) or stimulus(i).

614

615   Code: eur:5-9-section-three-three-one-four-one

616   Subsection of: eur:5-9-section-three-three-one-four with position: 1.

617   PharmML slot: ps:model-OVLinksToDrug-OV4.

618   Non-PharmML slot: ps:model-OVLinksToDrug-OV4.

619   Allows freetext alternative: false.

Section 3.3.1.4.2: OV4's nature of the variable.

620

621   Code: eur:5-9-section-three-three-one-four-two

622   Subsection of: eur:5-9-section-three-three-one-four with position: 2.

623   PharmML slot: ps:model-OVHasNature-OV4.

624   Non-PharmML slot: ps:model-OVHasNature-OV4.

625   Allows freetext alternative: false.

Section 3.3.1.4.3: OV4's units.

626

627   Code: eur:5-9-section-three-three-one-four-three

628   Subsection of: eur:5-9-section-three-three-one-four with position: 3.

629   PharmML slot: ps:model-OVHasUnits-OV4.

630   Non-PharmML slot: ps:model-OVHasUnits-OV4.

631   Allows freetext alternative: false.

Section 3.3.1.4.4: OV4's type of matrix.

632

Code: eur:5-9-section-three-three-one-four-four

633

Subsection of: eur:5-9-section-three-three-one-four with position: 4.

634

PharmML slot: ps:model-OVHasMatrixType-OV4.

635

Non-PharmML slot: ps:model-OVHasMatrixType-OV4.

636

Allows freetext alternative: false.

637

Section 3.3.1.4.5: OV4's type of observed variable.

638

Code: eur:5-9-section-three-three-one-four-five

639

Subsection of: eur:5-9-section-three-three-one-four with position: 5.

640

PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV4.

641

Non-PharmML slot: ps:model-OVHasTypeOfObservedVariable-OV4.

642

Allows freetext alternative: false.

643

Section 3.3.1.5: Observed variable 5.

644

Code: eur:5-9-section-three-three-one-five

645

Subsection of: eur:5-9-section-three-three-one with position: 5.

646

PharmML slot: NA.

647

Non-PharmML slot: NA.

648

Allows freetext alternative: false.

649

Section 3.3.1.5.1: OV5's Link to studied drug(s) or stimulus(i).

650

Code: eur:5-9-section-three-three-one-five-one

651

Subsection of: eur:5-9-section-three-three-one-five with position: 1.

652

PharmML slot: ps:model-OVLinksToDrug-OV5.

653

Non-PharmML slot: ps:model-OVLinksToDrug-OV5.

654

Allows freetext alternative: false.

655

Section 3.3.1.5.2: OV5's nature of the variable.

656

Code: eur:5-9-section-three-three-one-five-two

657

Subsection of: eur:5-9-section-three-three-one-five with position: 2.

658

PharmML slot: ps:model-OVHasNature-OV5.

659

Non-PharmML slot: ps:model-OVHasNature-OV5.

660

Allows freetext alternative: false.

661

Section 3.3.1.5.3: OV5's units.

662

663   <u>Code:</u> eur:5-9-section-three-three-one-five-three
664   <u>Subsection of:</u> eur:5-9-section-three-three-one-five with position: 3.
665   <u>PharmML slot:</u> ps:model-OVHasUnits-OV5.
666   <u>Non-PharmML slot:</u> ps:model-OVHasUnits-OV5.
667   <u>Allows freetext alternative:</u> false.

Section 3.3.1.5.4: OV5's type of matrix.

668

669   <u>Code:</u> eur:5-9-section-three-three-one-five-four
670   <u>Subsection of:</u> eur:5-9-section-three-three-one-five with position: 4.
671   <u>PharmML slot:</u> ps:model-OVHasMatrixType-OV5.
672   <u>Non-PharmML slot:</u> ps:model-OVHasMatrixType-OV5.
673   <u>Allows freetext alternative:</u> false.

Section 3.3.1.5.5: OV5's type of observed variable.

674

675   <u>Code:</u> eur:5-9-section-three-three-one-five-five
676   <u>Subsection of:</u> eur:5-9-section-three-three-one-five with position: 5.
677   <u>PharmML slot:</u> ps:model-OVHasTypeOfObservedVariable-OV5.
678   <u>Non-PharmML slot:</u> ps:model-OVHasTypeOfObservedVariable-OV5.
679   <u>Allows freetext alternative:</u> false.

Section 3.3.2: Link to studied drug(s) or stimulus(i).

680

681   <u>Code:</u> eur:5-9-section-three-three-two
682   <u>Subsection of:</u> eur:5-9-section-three-three with position: 2.
683   <u>PharmML slot:</u> NA.
684   <u>Non-PharmML slot:</u> NA.
685   <u>Allows freetext alternative:</u> false.

Section 3.3.3: Nature of the variable.

686

687   <u>Code:</u> eur:5-9-section-three-three-three
688   <u>Subsection of:</u> eur:5-9-section-three-three with position: 3.
689   <u>PharmML slot:</u> NA.
690   <u>Non-PharmML slot:</u> NA.
691   <u>Allows freetext alternative:</u> false.

Section 3.3.4: Units.

693   Code: eur:5-9-section-three-three-four

694   Subsection of: eur:5-9-section-three-three with position: 4.

695   PharmML slot: NA.

696   Non-PharmML slot: NA.

697   Allows freetext alternative: false.

Section 3.3.6: Type of observed variable.

699   Code: eur:5-9-section-three-three-six

700   Subsection of: eur:5-9-section-three-three with position: 6.

701   PharmML slot: NA.

702   Non-PharmML slot: NA.

703   Allows freetext alternative: false.

Section 3.3.7: Information collected.

705   Code: eur:5-9-section-three-three-seven

706   Subsection of: eur:5-9-section-three-three with position: 7.

707   PharmML slot: NA.

708   Non-PharmML slot: NA.

709   Allows freetext alternative: false.

Section 3.3.7.2: Number of subjects.

711   Code: eur:5-9-section-three-three-seven-two

712   Subsection of: eur:5-9-section-three-three-seven with position: 2.

713   PharmML slot: ps:trialdesign-HasAssociatedNumberOfSubjects-DataPool.

714   Non-PharmML slot: ps:model-HasAssociatedNumberOfSubjects-DataPool.

715   Allows freetext alternative: false.

Section 3.3.7.3: Number of modelled observations.

717   Code: eur:5-9-section-three-three-seven-three

718   Subsection of: eur:5-9-section-three-three-seven with position: 3.

719   PharmML slot: ps:trialdesign-HasAssociatedNumberOfModelledObservations-DataPool.

720   Non-PharmML slot: ps:model-HasAssociatedNumberOfModelledObservations-DataPool.

721   Allows freetext alternative: false.

Section 3.3.7.5: Sampling design specificities.

Code: eur:5-9-section-three-three-seven-five

Subsection of: eur:5-9-section-three-three-seven with position: 5.

PharmML slot: ps:trialdesign-HasAssociatedSamplingDesign-DataPool.

Non-PharmML slot: ps:model-HasAssociatedSamplingDesign-DataPool.

Allows freetext alternative: false.

Section 3.3.7.6: Dataset origin.

Code: eur:5-9-section-three-three-seven-six

Subsection of: eur:5-9-section-three-three-seven with position: 6.

PharmML slot: ps:trialdesign-observed-variables-are-real-freetext.

Non-PharmML slot: ps:model-observed-variables-are-real-freetext.

Allows freetext alternative: false.

Section 4: Model(s).

Code: eur:5-9-section-four

Subsection of: eur:5-9-eur with position: 4.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 4.1: Structural model characteristics.

Code: eur:5-9-section-four-one

Subsection of: eur:5-9-section-four with position: 1.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 4.1.0: Structural model characteristics present.

Code: eur:5-9-section-four-one

Subsection of: eur:5-9-section-four with position: 0.

PharmML slot: ps:structuralmodel-HasComponentType.

Non-PharmML slot: ps:model-HasComponentType.

Allows freetext alternative: false.

Section 4.1.1: PK component(s).

752

753   Code: eur:5-9-section-four-one-one
754   Subsection of: eur:5-9-section-four-one with position: 1.
755   PharmML slot: NA.
756   Non-PharmML slot: NA.
757   Allows freetext alternative: false.

Section 4.1.1.1: Input.

758

759   Code: eur:5-9-section-four-one-one-one
760   Subsection of: eur:5-9-section-four-one-one with position: 1.
761   PharmML slot: NA.
762   Non-PharmML slot: NA.
763   Allows freetext alternative: false.

Section 4.1.1.1.1: Input type.

764

765   Code: eur:5-9-section-four-one-one-one-one
766   Subsection of: eur:5-9-section-four-one-one-one with position: 1.
767   PharmML slot: ps:modeldefinition-HasAssociatedInputType.
768   Non-PharmML slot: ps:model-HasAssociatedInputType.
769   Allows freetext alternative: false.

Section 4.1.1.1.2: Absorption delay model.

770

771   Code: eur:5-9-section-four-one-one-one-two
772   Subsection of: eur:5-9-section-four-one-one-one with position: 2.
773   PharmML slot: ps:modeldefinition-HasAssociatedAbsorptionDelayModelType.
774   Non-PharmML slot: ps:model-HasAssociatedAbsorptionDelayModelType.
775   Allows freetext alternative: true.

Section 4.1.1.1.3: Absorption rate model for indirect input.

776

777   Code: eur:5-9-section-four-one-one-one-three
778   Subsection of: eur:5-9-section-four-one-one-one with position: 3.
779   PharmML slot: ps:modeldefinition-HasAssociatedAbsorptionRateType.
780   Non-PharmML slot: ps:model-HasAssociatedAbsorptionRateType.
781   Allows freetext alternative: true.

Section 4.1.1.1.4: Bioavailability for indirect input.

782

783   Code: eur:5-9-section-four-one-one-one-four
784   Subsection of: eur:5-9-section-four-one-one-one with position: 4.
785   PharmML slot: ps:modeldefinition-HasAssociatedBioavailabilityType.
786   Non-PharmML slot: ps:model-HasAssociatedBioavailabilityType.
787   Allows freetext alternative: true.

Section 4.1.1.1.5: Formation from another substance.

788

789   Code: eur:5-9-section-four-one-one-one-five
790   Subsection of: eur:5-9-section-four-one-one-one with position: 5.
791   PharmML slot: ps:modeldefinition-InputPresentsFormationFromOtherSubstance-string.
792   Non-PharmML slot: ps:model-InputPresentsFormationFromOtherSubstance-string.
793   Allows freetext alternative: false.

Section 4.1.1.1.6: Formation from substance.

794

795   Code: eur:5-9-section-four-one-one-one-six
796   Subsection of: eur:5-9-section-four-one-one-one with position: 6.
797   PharmML slot: ps:modeldefinition-InputPresentsFormationFromOtherSubstanceType.
798   Non-PharmML slot: ps:model-InputPresentsFormationFromOtherSubstanceType.
799   Allows freetext alternative: false.

Section 4.1.1.1.7: Nature of formation.

800

801   Code: eur:5-9-section-four-one-one-one-seven
802   Subsection of: eur:5-9-section-four-one-one-one with position: 7.
803   PharmML slot: ps:modeldefinition-InputPresentsFormationFromOtherSubstanceModelType.
804   Non-PharmML slot: ps:model-InputPresentsFormationFromOtherSubstanceModelType.
805   Allows freetext alternative: true.

Section 4.1.1.2: Distribution.

806

807   Code: eur:5-9-section-four-one-one-two
808   Subsection of: eur:5-9-section-four-one-one with position: 2.
809   PharmML slot: NA.
810   Non-PharmML slot: NA.
811   Allows freetext alternative: false.

Section 4.1.1.2.1: Number of distribution compartments (1 to X) (including the central compartment).

812
813

814   Code: eur:5-9-section-four-one-one-two-one
815   Subsection of: eur:5-9-section-four-one-one-two with position: 1.
816   PharmML slot: ps:modeldefinition-HasAssociatedNumberOfModelledCompartments.
817   Non-PharmML slot: ps:model-HasHassociatedNumberOfModelledCompartments.
818   Allows freetext alternative: false.

Section 4.1.1.2.2: Enterohepatic recycling.

819

820   Code: eur:5-9-section-four-one-one-two-two
821   Subsection of: eur:5-9-section-four-one-one-two with position: 2.
822   PharmML slot: ps:modeldefinition-HasAssociatedDistributionModellingAttribute-EnterohepaticRecycling.
823   Non-PharmML slot: ps:model-HasAssociatedDistributionModellingAttribute-EnterohepaticRecycling.
824   Allows freetext alternative: false.

Section 4.1.1.2.3: Non-linear transport.

825

826   Code: eur:5-9-section-four-one-one-two-three
827   Subsection of: eur:5-9-section-four-one-one-two with position: 3.
828   PharmML slot: ps:modeldefinition-HasAssociatedDistributionModellingAttribute-NonLinearTransport.
829   Non-PharmML slot: ps:model-HasAssociatedDistributionModellingAttribute-NonLinearTransport.
830   Allows freetext alternative: false.

Section 4.1.1.2.4: Non-linear protein binding.

831

832   Code: eur:5-9-section-four-one-one-two-four
833   Subsection of: eur:5-9-section-four-one-one-two with position: 4.
834   PharmML slot: ps:modeldefinition-HasAssociatedDistributionModellingAttribute-NonLinearProteinBinding
835   Non-PharmML slot: ps:model-HasAssociatedDistributionModellingAttribute-NonLinearProteinBinding.
836   Allows freetext alternative: false.

Section 4.1.1.2.5: Other distribution feature:.

837

838   Code: eur:5-9-section-four-one-one-two-five
839   Subsection of: eur:5-9-section-four-one-one-two with position: 5.
840   PharmML slot: ps:modeldefinition-HasAssociatedDistributionModellingAttribute-string.
841   Non-PharmML slot: ps:model-HasAssociatedDistributionModellingAttribute-string.
842   Allows freetext alternative: false.

Section 4.1.1.3: Elimination.

844 Code: eur:5-9-section-four-one-one-three
845 Subsection of: eur:5-9-section-four-one-one with position: 3.
846 PharmML slot: NA.
847 Non-PharmML slot: NA.
848 Allows freetext alternative: false.

Section 4.1.1.3.1: Compartment of elimination.

850 Code: eur:5-9-section-four-one-one-three-one
851 Subsection of: eur:5-9-section-four-one-one-three with position: 1.
852 PharmML slot: ps:modeldefinition-HasAssociatedEliminationModellingAttribute-CompartmentOfEliminati
853 Non-PharmML slot: ps:model-HasAssociatedEliminationModellingAttribute-CompartmentOfElimination.
854 Allows freetext alternative: false.

Section 4.1.1.3.2: Nature of elimination.

856 Code: eur:5-9-section-four-one-one-three-two
857 Subsection of: eur:5-9-section-four-one-one-three with position: 2.
858 PharmML slot: ps:modeldefinition-HasAssociatedEliminationModellingAttribute-TypeOfElimination.
859 Non-PharmML slot: ps:model-HasAssociatedEliminationModellingAttribute-TypeOfElimination.
860 Allows freetext alternative: false.

Section 4.1.2: PD component(s).

862 Code: eur:5-9-section-four-one-two
863 Subsection of: eur:5-9-section-four-one with position: 2.
864 PharmML slot: NA.
865 Non-PharmML slot: NA.
866 Allows freetext alternative: false.

Section 4.1.2.1: Disease/physiological system model (i.e., drug freee).

868 Code: eur:5-9-section-four-one-two-one
869 Subsection of: eur:5-9-section-four-one-two with position: 1.
870 PharmML slot: ps:modeldefinition-HasAssociatedModelledDrugFreeSystemType.
871 Non-PharmML slot: ps:model-HasAssociatedModelledDrugFreeSystemType.
872 Allows freetext alternative: false.

Section 4.1.2.2: Drug effect model.

874   <u>Code:</u> eur:5-9-section-four-one-two-two

875   <u>Subsection of:</u> eur:5-9-section-four-one-two with position: 2.

876   <u>PharmML slot:</u> NA.

877   <u>Non-PharmML slot:</u> NA.

878   <u>Allows freetext alternative:</u> false.

Section 4.1.2.2.1: Driver of drug effect.

880   <u>Code:</u> eur:5-9-section-four-one-two-two-one

881   <u>Subsection of:</u> eur:5-9-section-four-one-two-two with position: 1.

882   <u>PharmML slot:</u> ps:modeldefinition-HasDriverOfDrugEffectTypeAttribute.

883   <u>Non-PharmML slot:</u> ps:model-HasDriverOfDrugEffectTypeAttribute.

884   <u>Allows freetext alternative:</u> false.

Section 4.1.2.2.2: Shape of drug effect.

886   <u>Code:</u> eur:5-9-section-four-one-two-two-two

887   <u>Subsection of:</u> eur:5-9-section-four-one-two-two with position: 2.

888   <u>PharmML slot:</u> ps:modeldefinition-HasShapeOfDrugEffectTypeAttribute.

889   <u>Non-PharmML slot:</u> ps:model-HasShapeOfDrugEffectTypeAttribute.

890   <u>Allows freetext alternative:</u> false.

Section 4.1.2.2.3: Temporal relation of drug effect to response.

892   <u>Code:</u> eur:5-9-section-four-one-two-two-three

893   <u>Subsection of:</u> eur:5-9-section-four-one-two-two with position: 3.

894   <u>PharmML slot:</u> ps:modeldefinition-HasTemporalRelationBetweenDrugEffectAndResponseTypeAttribute.

895   <u>Non-PharmML slot:</u> ps:model-HasTemporalRelationBetweenDrugEffectAndResponseTypeAttribute.

896   <u>Allows freetext alternative:</u> false.

Section 4.1.2.3: Response model.

898   <u>Code:</u> eur:5-9-section-four-one-two-three

899   <u>Subsection of:</u> eur:5-9-section-four-one-two with position: 3.

900   <u>PharmML slot:</u> ps:modeldefinition-HasModelForResponseType.

901   <u>Non-PharmML slot:</u> ps:model-HasModelForResponseType.

902   <u>Allows freetext alternative:</u> false.

Section 4.1.4: Drug-drug interaction.

Code: eur:5-9-section-four-one-four
Subsection of: eur:5-9-section-four-one with position: 4.
PharmML slot: NA.
Non-PharmML slot: NA.
Allows freetext alternative: false.

Section 4.1.4.1: List of interacting drugs.

Code: eur:5-9-section-four-one-four-one
Subsection of: eur:5-9-section-four-one-four with position: 1.
PharmML slot: ps:trialdesign-hasListOfInteractingDrugs-freetext.
Non-PharmML slot: ps:model-hasListOfInteractingDrugs-freetext.
Allows freetext alternative: false.

Section 4.1.4.2: Mechanism of interaction.

Code: eur:5-9-section-four-one-four-two
Subsection of: eur:5-9-section-four-one-four with position: 2.
PharmML slot: NA.
Non-PharmML slot: NA.
Allows freetext alternative: false.

Section 4.1.4.2.1: Acting drug(s) or observed variable(s).

Code: eur:5-9-section-four-one-four-two-one
Subsection of: eur:5-9-section-four-one-four-two with position: 1.
PharmML slot: ps:trialdesign-hasInteractorByNickname-freetext.
Non-PharmML slot: ps:model-hasInteractorByNickname-freetext.
Allows freetext alternative: false.

Section 4.1.4.2.2: Acted on drug(s) or observed variable(s).

Code: eur:5-9-section-four-one-four-two-two
Subsection of: eur:5-9-section-four-one-four-two with position: 2.
PharmML slot: ps:trialdesign-hasInteracteeByNickname-freetext.
Non-PharmML slot: ps:model-hasInteracteeByNickname-freetext.
Allows freetext alternative: false.

Section 4.1.4.2.3: Type of model component impacted.

Code: eur:5-9-section-four-one-four-two-three

Subsection of: eur:5-9-section-four-one-four-two with position: 3.

PharmML slot: ps:trialdesign-hasTypeOfModelComponentImpacted.

Non-PharmML slot: ps:model-hasTypeOfModelComponentImpacted.

Allows freetext alternative: false.

Section 4.6: Noteworthy model assumptions or limitations.

Code: eur:5-9-section-four-six

Subsection of: eur:5-9-section-four with position: 6.

PharmML slot: ps:model-HasAssumptions-freetext.

Non-PharmML slot: ps:model-HasAssumptions-freetext.

Allows freetext alternative: false.

Section 5: Task execution.

Code: eur:5-9-section-five

Subsection of: eur:5-9-eur with position: 5.

PharmML slot: NA.

Non-PharmML slot: NA.

Allows freetext alternative: false.

Section 5.1: Software used to run the model.

Code: eur:5-9-section-five-one

Subsection of: eur:5-9-section-five with position: 1.

PharmML slot: ps:modellingstep-modelrun-uses-software.

Non-PharmML slot: ps:model-modelrun-uses-software.

Allows freetext alternative: true.