

# Enhanced Form Logic Guidance

**Implementation in EudraCT V8.1**

**Document Version 1.0**

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## Enhanced Form Logic – EudraCT V8.1

*In EudraCT v8.1 When specific values are entered into certain fields in an entry form, this will also auto fill other relevant fields without requiring a manual input. The enhanced form logic is based on the following criteria:*

- Auto-population of child/dependant fields with the contents of parent fields to make the form sections easier and quicker to fill in, reducing the amount of duplicate data entry*
- Auto-population of child/dependent fields is only activated on initial data entry but subsequent changes/corrections of the parent field are not carried over to child fields. E.g A.1 Member state in which the submission is being made will be auto filled in D.2.1.2, Country that granted the MA, however if the user changes the value in A.1, the update will not be cascaded to D.2.1.2*
- For subsequent changes/corrections, the child/dependent fields need to be updated manually – they do not change automatically. This approach is taken to avoid users having entered data changed or deleted without their knowledge*

# Enhanced Form Logic – Example of auto population

*D.2.1.2 The country that granted the marketing authorisation and D.2.1.2.1 Is this MS concerned with this application is auto populated on the basis of A.1 Member state in which the submission is being made*

The screenshot shows a web form with the following fields and values:

- Initial Required Information**
  - National Competent Authority:** Finland - Fimea (highlighted with a red box)
  - EudraCT Number:** 2011-002266-20
- D.2.1.2 The country which granted the Marketing Authorisation:** Finland (highlighted with a red box)
- D.2.1.2.1 Is this the Member State concerned with this application?:** Yes (radio button selected, highlighted with a red box)

**Please note** if you change or update the entry in A.1 from Finland to some other country, the change will not be cascaded to D.2.1.2 / D.2.1.2.1. This update or correction will have to be entered manually as the logic is only supported on initial data entry.

# Enhanced Form Logic – Example of hiding non applicable questions

If F.1.1 Are the trial subjects less than 18 years answered = 'no', all sub questions upto F.1.1.6.1 are hidden.

**F. Population of Trial Subjects**

**F.1 Age Range**

F.1.1 Are the trial subjects under 18?  Yes  No  Not Answered ?

F.1.2 Adults (18-64 years)  Yes  No  Not Answered ?

These questions are displayed if F.1.1 = 'yes'

**F.1 Age Range**

F.1.1 Are the trial subjects under 18?  Yes  No  Not Answered ?

Number of subjects for this age range:  ?

F.1.1.1 In Utero  Yes  No  Not Answered ?

F.1.1.1.1 Number of subjects for this age range:  ?

F.1.1.2 Preterm newborn infants (up to gestational age < 37 weeks)  Yes  No  Not Answered ?

F.1.1.2.1 Number of subjects for this age range:  ?

F.1.1.3 Newborns (0-27 days)  Yes  No  Not Answered ?

F.1.1.3.1 Number of subjects for this age range:  ?

F.1.1.4 Infants and toddlers (28 days-23 months)  Yes  No  Not Answered ?

F.1.1.4.1 Number of subjects for this age range:  ?

F.1.1.5 Children (2-11years)  Yes  No  Not Answered ?

F.1.1.5.1 Number of subjects for this age range:  ?

F.1.1.6 Adolescents (12-17 years)  Yes  No  Not Answered ?

F.1.1.6.1 Number of subjects for this age range:  ?

# Enhanced Form Logic

## Listing of Fields by CTA Section

Note: Please refer to the Clinical Trial Application (CTA) Form for field descriptions for field identifiers referenced in these slides

## B.2 Legal Representative

- *When the sponsor is located in a EEA country i.e. B.1.3.4 = EEA, the legal representative section B.2 could be hidden*

## C.1.1 And C.1.2 Sponsor Information/Legal Representative

*Automatic load of sponsor information if the sponsor is also an applicant. Likewise auto population of legal representative information if the legal rep is also an applicant.*

- If question C.1.1, value = Sponsor, the Applicant information should be auto-filled with the Sponsor information in section C.1.4.1 upto C.1.4.6. The info will be auto populated from B.1*
- Likewise, if C.1.2 value = The Legal Representative, the Applicant information should be auto filled with the Legal representative information in C.1.4.1 upto C.1.4.6. The info will be auto populated from Section B.2*

## Section D.2

*CTA sub questions dependent on a Yes answer to a parent/root question are hidden by default. They are displayed if the answer to the root question is Yes.*

- D.2.1.1.4.1 should only be displayed if D.2.1.1.4 is answered Yes*
- D.2.5.1. should only be displayed if D.2.5 is answered Yes*
- D.2.6.1.1 and D.2.6.1.2. should only be displayed if D.2.6.1. is answered Yes*



## D.2.1.2.1

- *D.2.1.2.1 Is this MS concerned with this application should be automatically answered on the basis of A.1 MS in which the submission is being made and D.2.1.2 The country that granted the marketing authorisation.*

## Section D.3

- *D.3.11.3.1, D.3.11.3.2, D.3.11.3.3, D.3.11.3.4, and D.3.11.3.5 should only be displayed if D.3.11.3 is yes*
- *D.3.11.3.5.1 should only be displayed if D.3.11.3.5 is answered Yes*
- *D.3.11.10.1 and D.3.11.10.2 should only be displayed if D.3.11.10 has been answered Yes*

## **D.3.6.1 And D.3.6.2**

- *Routes of administration in D.3.6.1 And D.3.6.2 should automatically be included in D.3.7*

## Section D.4, D.5, D.6 continued..

- *D.4.1.3.1 should only be displayed if D.4.1.3 is answered Yes*
- *D.4.2.2.1 should only be displayed if D.4.2.2 is answered Yes*
- *D.4.2.3.1 should only be displayed if D.4.2.3 is answered Yes*
  
- *D.5.4.1.1 and D.5.4.1.2 should only be displayed if D.5.4.1 is answered Yes*
- *D.5.4.2.1 should only be displayed if D.5.4.2 is answered Yes*
- *D.5.4.3.1 should only be displayed if D.5.4.3 is answered Yes*
- *D.5.5.3.1 should only be displayed if D.5.3.3 is answered Yes*
  
- *D.6.1.3.1 should only be displayed if D.6.3.1 is answered Yes*
- *D.6.2.2.1 should only be displayed if D.6.2.2 is answered Yes*
- *D.6.2.3.1 should only be displayed if D.6.2.3 is answered Yes*

## Section D.7

- *D.7.4.1.1. should only be displayed if D.7.4.1. is answered Yes*
- *D.7.4.1.1.1. should only be displayed if D.7.4.1.1. is answered Yes*
- *D.7.4.5.1 should only be displayed if D.7.4.5 is answered Yes*

## Section D.8

- *D.8.5.2.1 should only be displayed if D.8.5.2. is answered No*

Implementation: Iteration 2

## Section E

- *E.7.1.1 to E.7.1.3.1 should only be displayed if E.7.1 answer is Yes.*

## E.8.1

- *E.8.1 and E.8.2 sub-questions until E.8.2.4 should be hidden and only displayed when E.8.1. is answered Yes*



## **F.1.1 Less than 18 years**

- *All sub questions dependent on F.1.1. upto F.1.1.6.1 should be hidden unless F.1.1. is answered Yes.*

## G.2.5.4 And H.2.24

- *G.2.5.4 and H.2.2.4 should have automatically written the country in A.1.*

Implementation: Iteration 2

## H.2.1

- *A1 Member state in which the submission is made should be automatically included in H.2.1 Name of Competent Authority*

# Annex - Enhanced Form Logic

**EudraCT V8 Behaviour**

## **EudraCT Version 8 – Enhanced Form Logic System Behaviour**

### **D.4, D.5, D.6, D.7**

- *D.4 is only displayed if D.3.11.3.1 is answered Yes*
- *D.5 is only displayed if D.3.11.3.2 is answered Yes*
- *D.6 is only displayed if D.3.11.3.3 is answered Yes*
- *D.7 is only displayed if either D.3.11.3.4. or D.3.11.4 are answered Yes*