



# BEST PRACTICE: ZA v3.1 JUNE 2025 DEFINED LIST UPDATES

# 1 Revision History

To ensure alignment with the latest regulatory requirements, Ennov follows a structured approach when Health Authorities release new specifications. For specifications with limited technical impact, Ennov's InSight Business Consulting Team conducts a thorough review and updates our Best Practice documentation.

<b>Software Version</b>	<b>Release/ Revision Date</b>	<b>Summary of Change(s)</b>
v7.x	20-June-2025	Initial Authoring
v7.x	26-June-2025	Update to sub-type-38 and sub-type-39 name pre update.
v7.x	26-June-2025	Update to section 4.6 to correct path. Other minor corrections.

## 2 Document Purpose & Scope

Ennov has implemented modifications in Ennov InSight to align with the ZA 3.1 defined list updates, which become mandatory for submissions starting 1st July 2025. This Best Practice provides instructions for publishing compliant eCTD assemblies.

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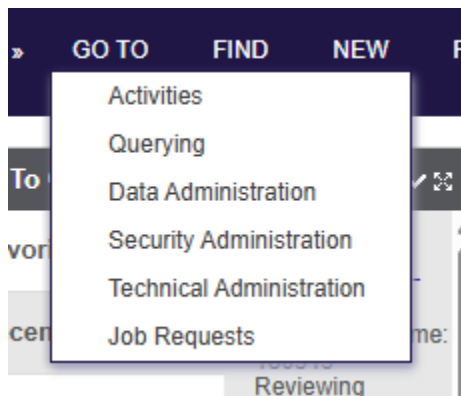
## 4 Best Practice on Adding/Editing ZA Values

Users should follow the steps below after receiving their DTD update for ZA. This best practice describes how to access Data Administration and update the values for several tables which relate to values updated/added/deleted in the latest defined list updates from SAHPRA.

### 4.1 Data Administration

To access Data Administration the user must do the following:

1. Log in to Ennov InSight.
2. Click Go-to on the top menu bar
3. Click Data Administration



### 4.2 Application Type Defined List Updates

#### 4.2.1 Create New Application Type Values

Before creating new Application Type Values the user must create a relevant Application Category. This can be found in Application Maintenance -> Application Category Values.

1. To add a value, click on the create button.

Application Category Values				
Return to menu				
Application Category ...	Last User Updated	Last Changed Date	Active Flag	

2. Create two values as shown in the table below.

## Application Category Value

### Emergency Use Listing

### REA - Work Sharing - Country

Now that the Application Category has been created, the Application Types may be created. The Data Administration Table relating to Application Types can be found in Application Maintenance -> Application Type Values.

#### Application Maintenance

- Age Span Population Values
- Application Category Values
- Application Status Values
- Application Type Values
- CTA Product Role Values

3. To add a value, click on the create button.

#### Application Type Values

[Return to menu](#)

Applicati...	Name	Display ...	Entity X...	Applicati...	Countries	Last Use...	Last Cha...	Active Flag
--------------	------	-------------	-------------	--------------	-----------	-------------	-------------	-------------

4. Create Application Type Values with the following attributes:
  - a. Application Type: as shown in the table below
  - b. Name: as shown in the table below
  - c. Display Name: as shown in the table below
  - d. Country: South Africa.
  - e. Entity XML: New Drug Application
  - f. Application Category: align with the value created previously

#### Application Type Values

Application Type: \*

Name: \*

Display Name: \*

Entity XML Type Name: \*

Application Category: \*

Countries:

Available Countries	Selected Countries
South Georgia and The South Sandwich Islands	South Africa
Spain	
Sri Lanka	
Sudan	
Suriname	

5. After creating a value, the user must create an Application Type eCTD Code. Click on the create button.

Application Type eCTD Code							
Applicabl...	eCTD Code	Agency A...	Countries	Limit to Cr...	Last User ...	Last Chan...	Active Flag
<input type="checkbox"/> za-3-1	app-type-2		South Africa	No	SYSMAINT	22-Aug-2024	Y

6. Create the Application Type eCTD code with the following attributes:
7. Applicable DTD/Schema: za-3-1
8. eCTD code: this is unique for each Application Type and can be found in the table below.

Applicable DTD/Schema: \*

eCTD Code: \*

Agency Abbreviation:

Limit to Cross Application Only: \*

Last User Updated: SYSMAINT

Last Changed Date: 24-Jul-2024

### Values to Add to Application Type Values

Application Type Value	Display Name/Name	eCTD Code
<b>Emergency Use Listing</b>	Emergency Use Listing	app-type-8
<b>REA - Work Sharing - Country</b>	REA - Work Sharing - Country	app-type-9

### 4.2.2 Edit Application Type Values

To edit an existing value the user must select the Application Type Value and click the edit button.

#### Application Type Values

◀ Back

Application Type: AMAP

Name: AMA Procedure

Display Name: AMA Procedure

Entity XML Type Name: New Drug Application

Application Category: AMA Procedure

Countries: South Africa

Last User Updated: SYSMAINT

Last Changed Date: 24-Jul-2024

Active Flag: Active

### Values to Edit in Application Type Values

Application Type Value	Updated Value/Name/Display Name	eCTD Code (Reference Only)
AMAP	REA - AMA Procedure	app-type-2
JR	RIA - ZAZIBONA Joint Review	app-type-3
WHO-PQ	RIA - WHO-PQ	app-type-4
WHO-CRP	RIA - WHO-SRA CRP	app-type-5
CH-GHP	RIA - Swissmedic MAGHP	app-type-6
EU-M4ALL	RIA - EU M4ALL	app-type-7


### 4.3 Submission Type Defined List Updates

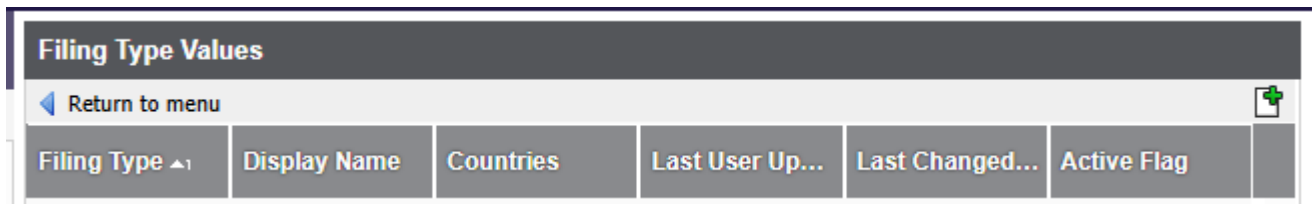
The Data Administration table relating to Submission Types can be found in Sequence Maintenance -> Filing Type Values.


#### 4.3.1 Create New Filing Type Values

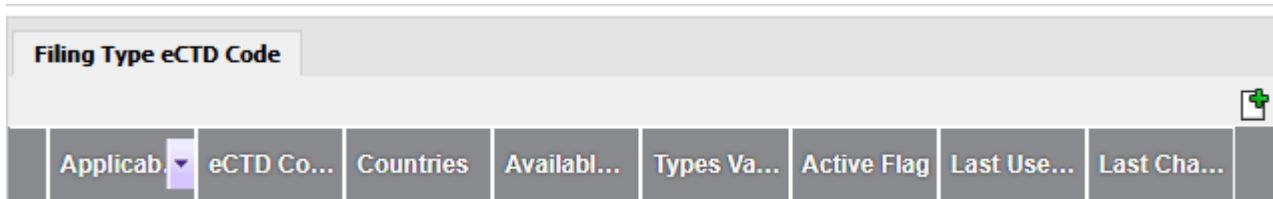
The instructions below describe how to create a value and a Filing Type eCTD Code. Use these in conjunction with the tables provided to ensure that the values are correct.



1. To add a value, click on the create button. 



2. Filing Type and Display Name should match the table below and the country should be South Africa.
3. After creating a value, the user must create a Filing Type eCTD Code. Click on the create button. 



4. The user must fill in the details for each new Filing Type eCTD Code with the following attributes.

- a. Applicable DTD/Schema: za-3-1
- b. eCTD code: this is unique for each Filing Type and can be found in the table below
- c. Available for Application Types: select all values.

Filing Type eCTD Code	
Filing Type:	D - New Generic Medicine
Display Name:	D - New Generic Medicine
Countries:	Australia, South Africa
Last User Updated:	SYSMANT
Last Changed Date:	22-Mar-2021
Active Flag:	Active
Applicable DTD/Schema:	* za-3-1
eCTD Code:	* sub-type-2
Available for Application Types:	* Available
	<div style="display: flex; align-items: center;"> <div style="border: 1px solid gray; padding: 2px; width: 200px; height: 40px; margin-right: 5px;"></div> <div style="margin-right: 5px;"> <input type="button" value="&gt;&gt;"/>  <input type="button" value="&lt;&lt;"/> </div> <div style="border: 1px solid gray; padding: 2px; width: 150px; height: 40px; margin-right: 5px;">                     Selected                      AMA Procedure                      Clinical Trial Authorisation                      Device Application                      EU M4ALL                      New Drug Application                 </div> </div>
Types Valid for Grouped Submissions:	Available
	<div style="display: flex; align-items: center;"> <div style="border: 1px solid gray; padding: 2px; width: 200px; height: 40px; margin-right: 5px;">                     EU M4ALL                      WHO SRA CRP                      WHO-PQ                      ZAZIBONA Joint Review                      SAHPRA National Procedure                 </div> <div style="margin-right: 5px;"> <input type="button" value="&gt;&gt;"/>  <input type="button" value="&lt;&lt;"/> </div> <div style="border: 1px solid gray; padding: 2px; width: 150px; height: 40px; margin-right: 5px;">                     Selected                 </div> </div>
Last User Updated:	SYSMANT
Last Changed Date:	22-Aug-2024

### Values to Add to Filing Type Values fields

Filing Type	Display Name	eCTD Code
<b>Type IB - Inspectorate</b>	Type IB - Inspectorate	sub-type-45
<b>z-Code - Type IAin</b>	z-Code - Type IAin	sub-type-47
<b>z-Code - Type IB</b>	z-Code - Type IB	sub-type-48
<b>Type II - Grouped Variation N and S</b>	Type II - Grouped Variation N and S	sub-type-49
<b>z-Code - Type IA</b>	z-Code - Type IA	sub-type-50

### 4.3.2 Edit Filing Type Values

To edit an existing value the user must select the existing Filing Type Value and click the edit button.

**Filing Type Values**

◀ Back
✎

Filing Type: Type IB-Clinical  
 Display Name: Type IB-Clinical  
 Countries: South Africa  
 Last User Updated: SYSMAINT  
 Last Changed Date: 22-Aug-2024  
 Active Flag: Active

### Values to Edit in Filing Type Values

Filing Type	Updated Value	eCTD Code
<b>Line extension-New Application</b>	Line extension - New Application (De-Linking of Application)	sub-type-14
<b>Type I-Inspectorate</b>	Type IA - Inspectorate	sub-type-22
<b>Type I-Other</b>	Type IAin - Inspectorate	sub-type-23
<b>z-Code-Quality</b>	z-code - Type II	sub-type-32
<b>Type IB-Related Clinical</b>	Grouped Variation Clinical	sub-type-38
<b>Type IB-Related Quality</b>	Grouped Variation Quality	sub-type-39
<b>Type IB-Related Inspectorate</b>	Grouped Variation Inspectorate	sub-type-40
<b>Type II-Related Inspectorate</b>	Type II - Inspectorate	sub-type-44

### 4.3.3 Deactivate Filing Type Values

To deactivate an existing value the user must select the existing Filing Type Value and click the edit button.



The user will have the option to deactivate the value, click on deactivate.

◀

✔ Save
 

Deactivate

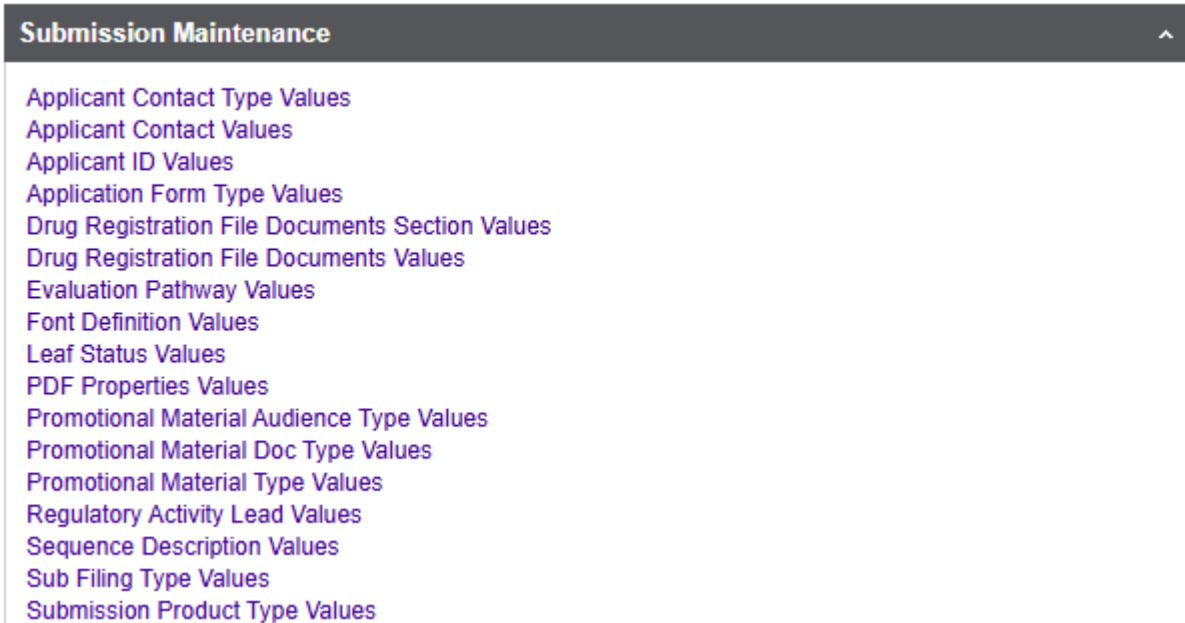
✖ Cancel

### Values to Deactivate in Filing Type Values

Filing Type	eCTD Code (Reference Only)
<b>Line extension-New Dosage Form</b>	sub-type-13
<b>Type II -Related Clinical</b>	sub-type-42
<b>Type II -Related Quality</b>	sub-type-43

## 4.4 Sequence Type Defined List Updates

The Data Administration Table relating to Sequence Types can be found in Sequence Maintenance -> Sub Filing Type Values. The instructions below describe how to create a value and edit existing values. Use this in conjunction with the tables provided to ensure that the values are correct.



### 4.4.1 Create New Sub Filing Type Values

1. To add a value, click on the create button.



2. Sub Filing Type values should match the table below and the country should be South Africa.
3. After creating a value, the user must create a Sub Filing Type eCTD Code. Click on the create button.



The screenshot shows the header of a table titled "Sub Filing Type eCTD Code". The table has the following columns:

Applicable...	eCTD Code	Countries	Available f...	Last User ...	Last Chan...	Active Flag
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4. The user must fill in the details as follows:
  - a. Applicable DTD/Schema: za-3-1
  - b. eCTD code: unique for each Sub Filing Type and can be found in the table below

c. Available for Application Types: select all values.

**Sub Filing Type eCTD Code**

Sub Filing Type: Response-Screening

Countries: South Africa

Last User Updated: Diarmuid WAIDE

Last Changed Date: 20-Jun-2025

Active Flag: Active

Applicable DTD/Schema: \* za-3-1

eCTD Code: \* sequence-type-13

Available for Filing Types: \* Available

▼

>>

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**Selected**  
 Applicant transfer, name and address change of applicant (post-reg-hcr)  
 Applicant transfer, name and address change of applicant (resp-post-reg-hcr)  
 Application Withdrawal/Cancellation  
 Baseline  
 Biological committee response (pre-reg-biol)

### Values to Add to Sub Filing Type Values

Filing Type	eCTD Code
<b>Response-Screening</b>	seq-type-13
<b>Response-HPA Cert.Variation</b>	seq-type-14
<b>Response-Clinical 2</b>	seq-type-15
<b>Response-Quality 2</b>	seq-type-16
<b>Response-Inspectorate 2</b>	seq-type-17
<b>Response-N and S 2</b>	seq-type-18
<b>Response-Biological 2</b>	seq-type-19
<b>Response-Renewals 2</b>	seq-type-20
<b>Response-PV 2</b>	seq-type-21

### 4.4.2 Edit Sub Filing Type Values

To edit an existing value the user must click on the Sub Filing Type Value and click the edit button.

**Sub Filing Type Values**

◀ Back

Sub Filing Type: Response-Renewals

Countries: South Africa

Last User Updated: SYSMIAINT


Last Changed Date: 24-Jul-2024

Active Flag: Active

### Values to Edit in Sub Filing Type Values

Sub Filing Type	Updated Value	eCTD Code (Reference Only)
Response-Clinical	Response-Clinical 1	seq-type-3
Response-Quality	Response-Quality 1	seq-type-4
Response-Inspectorate	Response-Inspectorate 1	seq-type-5
Response-N and S	Response-N and S 1	seq-type-6
Response-Biological	Response-Biological 1	seq-type-10
Response-Renewals	Response-Renewals 1	seq-type-11
Response-PV	Response-PV 1	seq-type-12

### 4.4.3 Deactivate Sub Filing Type Values

To deactivate an existing value the user must click on the Sub Filing Type Value and click the edit button. 

The user will have the option to deactivate the value, click on deactivate.



### Values to Deactivate in Sub Filing Type Values

Existing Sub Filing Type	eCTD Code (Reference Only)
Work Grouping Partial Withdrawal	seq-type-8

## 4.5 Evaluation Pathway Defined List Updates

The Data Administration Table relating to Evaluation Pathways can be found in Sequence Maintenance -> Evaluation Pathway Values. The instructions below describe how to edit the value that was updated in the new defined list files.

### Submission Maintenance

- [Applicant Contact Type Values](#)
- [Applicant Contact Values](#)
- [Applicant ID Values](#)
- [Application Form Type Values](#)
- [Drug Registration File Documents Section Values](#)
- [Drug Registration File Documents Values](#)
- [Evaluation Pathway Values](#)
- [Font Definition Values](#)

1. Once in the Evaluation Pathway Values table select the following value.

South Africa	za-3-1	eval-path-5	Section 21	SYSMAINT	24-Jul-2024	Active
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2. Click the edit button
3. Update the Evaluation Pathway Value to "Section 21/EUL".

**Evaluation Pathway Values**

Region: \*

Applicable DTD/Schema: \*

eCTD Code: \*

Evaluation Pathway: \*

Last User Updated: SYSMAINT

Last Changed Date: 24-Jul-2024

## 4.6 Submission Lead Defined List Updates

The Data Administration Table relating to Submission Lead can be found in Sequence Maintenance -> Regulatory Activity Lead Values. The instructions below describe how to edit the value that was updated in the new defined list files.

### 4.6.1 Create New Submission Lead Value

1. To add a value, click on the create button.

**Regulatory Activity Lead Values**

[Return to menu](#)

Region ▲	eCTD Code	Regulatory...	Applicable ...	Last User ...	Last Chan...	Active Flag
----------	-----------	---------------	----------------	---------------	--------------	-------------

2. Regulatory Activity Lead values should match the table below and the country should be South Africa.
3. The user must fill in the details as follows:
  - a. Applicable DTD/Schema: za-3-1
  - b. eCTD code: sub-lead-7
  - c. Regulatory Activity Lead: Medical Device

Regulatory Activity Lead Values	
Region:	* South Africa
eCTD Code:	* sub-lead-7
Regulatory Activity Lead:	* Medical Devices
Applicable DTD/Schema:	* za-3-1

### Values to Add to Submission Lead

Submission Lead Value	eCTD Code
Medical Devices	sub-lead-7

## 4.6.2 Edit Submission Lead Values

- Submission Maintenance**
- Applicant Contact Type Values
  - Applicant Contact Values
  - Applicant ID Values
  - Application Form Type Values
  - Drug Registration File Documents Section Values
  - Drug Registration File Documents Values
  - Evaluation Pathway Values
  - Font Definition Values
  - Leaf Status Values
  - PDF Properties Values
  - Promotional Material Audience Type Values
  - Promotional Material Doc Type Values
  - Promotional Material Type Values
  - Regulatory Activity Lead Values
  - Sequence Description Values

1. Once in the Regulatory Activity Lead Values table select the following value.

South Africa	sub-lead-2	Complimentary	za-3-1
--------------	------------	---------------	--------

2. Click the edit button.
3. Update the Evaluation Pathway Value to "Complementary".

Regulatory Activity Lead Values	
Region:	* <input type="text" value="South Africa"/>
eCTD Code:	* <input type="text" value="sub-lead-2"/>
Regulatory Activity Lead:	* <input type="text" value="Complementary"/>
Applicable DTD/Schema:	* <input type="text" value="za-3-1"/>
Last User Updated:	SYSMAINT
Last Changed Date:	24-Jul-2024

## 5 Checklist

Below is a list of all values that should be added/edited sorted by Data Admin Table which can be used to track what has been performed.

### 5.1 Application Category

Location: Application Maintenance -> Application Category Values

#### 5.1.1 New Values

Application Category Value
<b>Emergency Use Listing</b>
<b>REA - Work Sharing - Country</b>

### 5.2 Application Type

Location: Application Maintenance -> Application Type Values

#### 5.2.1 New Values

Application Type Value	Display Name/Name	eCTD Code
<b>Emergency Use Listing</b>	Emergency Use Listing	app-type-8
<b>REA - Work Sharing - Country</b>	REA - Work Sharing - Country	app-type-9

#### 5.2.2 Edited Values

Existing Application Type Value	Updated Value/Name/Display Name	eCTD Code (Reference Only)
<b>AMAP</b>	REA - AMA Procedure	app-type-2
<b>JR</b>	RIA - ZAZIBONA Joint Review	app-type-3
<b>WHO-PQ</b>	RIA - WHO-PQ	app-type-4
<b>WHO-CRP</b>	RIA - WHO-SRA CRP	app-type-5
<b>CH-GHP</b>	RIA - Swissmedic MAGHP	app-type-6
<b>EU-M4ALL</b>	RIA - EU M4ALL	app-type-7

### 5.3 Submission Type

Location: Submission Maintenance -> Filing Type

### 5.3.1 New Values

Filing Type	Display Name	eCTD Code
<b>Type IB - Inspectorate</b>	Type IB - Inspectorate	sub-type-45
<b>z-Code - Type IAin</b>	z-Code - Type IAin	sub-type-47
<b>z-Code - Type IB</b>	z-Code - Type IB	sub-type-48
<b>Type II - Grouped Variation N and S</b>	Type II - Grouped Variation N and S	sub-type-49
<b>z-Code - Type IA</b>	z-Code - Type IA	sub-type-50

### 5.3.2 Edited Values

Filing Type	Updated Value	eCTD Code
<b>Line extension - New Application</b>	Line extension - New Application (De-Linking of Application)	sub-type-14
<b>Type I-Inspectorate</b>	Type IA - Inspectorate	sub-type-22
<b>Type I-Other</b>	Type IAin - Inspectorate	sub-type-23
<b>z-Code-Quality</b>	z-code - Type II	sub-type-32
<b>Type IB-Related Clinical</b>	Grouped Variation Clinical	sub-type-38
<b>Type IB-Related Quality</b>	Grouped Variation Quality	sub-type-39
<b>Type IB-Related Inspectorate</b>	Grouped Variation Inspectorate	sub-type-40

### 5.3.3 Deactivated Values

Filing Type	eCTD Code (Reference Only)
<b>Line extension–New Dosage Form</b>	sub-type-13
<b>Type II - Related Clinical</b>	sub-type-42
<b>Type II - Related Quality</b>	sub-type-43

## 5.4 Sequence Type

Location: Submission Maintenance -> Sub Filing Type

### 5.4.1 New Values

<b>Filing Type</b>	<b>eCTD Code</b>
<b>Response-Screening</b>	seq-type-13
<b>Response-HPA Cert.Variation</b>	seq-type-14
<b>Response-Clinical 2</b>	seq-type-15
<b>Response-Quality 2</b>	seq-type-16
<b>Response-Inspectorate 2</b>	seq-type-17
<b>Response-N and S 2</b>	seq-type-18
<b>Response-Biological 2</b>	seq-type-19
<b>Response-Renewals 2</b>	seq-type-20
<b>Response-PV 2</b>	seq-type-21

### 5.4.2 Edited Values

<b>Existing Sub Filing Type</b>	<b>Updated Value</b>	<b>eCTD Code (Reference Only)</b>
<b>Response-Clinical</b>	Response-Clinical 1	seq-type-3
<b>Response-Quality</b>	Response-Quality 1	seq-type-4
<b>Response-Inspectorate</b>	Response-Inspectorate 1	seq-type-5
<b>Response-N and S</b>	Response-N and S 1	seq-type-6
<b>Response-Biological</b>	Response-Biological 1	seq-type-10
<b>Response-Renewals</b>	Response-Renewals 1	seq-type-11
<b>Response-PV</b>	Response-PV 1	seq-type-12

### 5.4.3 Deactivated Values

<b>Existing Sub Filing Type</b>	<b>eCTD Code (Reference Only)</b>
<b>Work Grouping Partial Withdrawal</b>	seq-type-8

## 5.5 Evaluation Pathway

Location: Sequence Maintenance -> Evaluation Pathway Values.

### 5.5.1 Edited Values

Existing Evaluation Pathway Value	Updated Value	eCTD Code (Reference Only)
<b>Section 21</b>	Section 21/EUL	eval-path-5

## 5.6 Submission Lead

Location: Sequence Maintenance -> Regulatory Activity Lead Values

### 5.6.1 New Values

Submission Lead Value	eCTD Code
<b>Medical Devices</b>	sub-lead-7

### 5.6.2 Edited Values

Existing Submission Lead Value	Updated Value	eCTD Code (Reference Only)
<b>Complimentary</b>	Complementary	sub-lead-2