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ECTD POINTS TO CONSIDER DOCUMENT

1.0 INTRODUCTION

1.1 Background

1.2 Implementation

1.3 Publishing Staff

1.4 Tools and tips

Health Authority Viewing tools, eCTD to paper considerations

2.0 OVERVIEW BY REGION

2.1 United States

2.1.1 Submission Types

To be included would be how/why what might be different (such as paper copies for Meeting Packages, Orphan Drug does not accept eCTD but does accept eSub).

2.1.1.1 IND

2.1.1.2 NDA

2.1.1.3 DMF

2.1.1.4 Orphan Drug

2.1.1.5 BLA

2.1.1.6 Advertising and Promotional

2.1.1.7 Meeting Requests

2.2 Europe

2.2.1 Submission Types

2.2.1.1 Centralized

2.2.1.2 MRP

2.2.1.3 DCP

2.2.1.4 National

2.2.1.5 CTA/IMPDs

2.3 Canada

2.3.1 Submission Types

2.3.1.1 NDS

2.4 Japan

2.4.1 Submission Types

2.4.1.1 MAAs

2.5 Australia

2.5.1 Submission Types

2.5.1.1 MAAs

3.0 GENERAL CONSIDERATIONS

3.1 Granularity – Overall CMC as well as further breaking down Clinical documents past E3

3.2 Attribute Information

3.2.1 STF vs node extensions vs file organization for Clinical

3.2.2 CMC attribute information for 3.2.S and 3.2.P and if they have to match 2.3.S and 2.3.P

3.2.3 Datasets

CDISC or not?, what to put in the eCTD when ECGs are submitted via the warehouse etc.

3.2.4 Cloning strategy

Giving Health Authorities what they didn't ask for

3.2.5 Publications/References – how to reference, when to include etc.

4.0 LIFECYCLE MANAGEMENT

4.1 Application

4.1.1 Related Sequences

4.1.2 Submission Types

4.1.3 Node Attribute information

i.e., (3.2.S, 3.2.P, 5.3.5 etc.) and the impact of Life-cycle, such as the decision to go with a more general attribute name for 3.2.S (company name vs. site name). STF Title information

4.2 Documents

4.2.1 Operators – tackle the “Append vs Replace” debate

4.2.2 Output file vs leaf title

4.2.3 Labeling Life-cycle – Draft, Final, SPC, PIM etc.

5.0 DOCUMENT LEVEL CONSIDERATIONS

5.1 Formatting

5.1.1 Headers and Footers

5.1.2 Tables of Contents

5.1.3 Referencing

5.1.4 Bookmarks

5.1.5 Hyperlinking

5.1.5.1 Where to link to – page vs. reference vs. TOC

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