独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

IMDRF RPS WGの活動について

（独）医薬品医療機器総合機構
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Pharmaceuticals and Medical Devices Agency

IMDRF RPS

Regulated Product Submission (RPS） WG

医療機器の電子申請に関する
標準仕様の構築を目指す

他国・多国への申請、他国からの申請の負担の軽減

outline

1.ToC

2.Dynamic Formatの開発

outline

1.ToC

2.Dynamic Formatの開発

ToC

Table of Contents (ToC)

各国の規制の要求事項をまとめ
体系を整理したインデックス

Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)
→ IMDRF/RPS WG/N9 FINAL:2019

In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)
→ IMDRF/RPS WG/N13 FINAL:2019

ToCの章分け

【non-IVD】（N9）

CHAPTER 1 – REGIONAL ADMINISTRATIVE
CHAPTER 2 – SUBMISSION CONTEXT
CHAPTER 3 – NON-CLINICAL EVIDENCE
CHAPTER 4 – CLINICAL EVIDENCE
CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL
CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES
CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION

【IVD】（N13）

CHAPTER 1 – REGIONAL ADMINISTRATIVE
CHAPTER 2 – SUBMISSION CONTEXT
CHAPTER 3 – ANALYTICAL PERFORMANCE AND OTHER EVIDENCE
CHAPTER 4 – CLINICAL EVIDENCE
CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL
CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES
CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION

Heading Class & Level

Common Content

このHeadingsに対する一般的な事項

Regional Content

Regionalな事項の詳細

IMDRF/RPS WG/N9 FINAL:2019 (Edition 3)

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
			k) Engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). l) ↓ **NOTE**: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device	
2.04.02	IMDRF (ANVISA, NMPA, EU, HC, HSA, TGA,	Description of Device Packaging	a) Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated; b) Specific packaging of accessories marketed together with the medical devices shall also be described; c) If the user needs to package the medical device or its accessories before they perform	

ToC

Heading Class （注）文書内の定義をご確認ください

IMDRF

共通のHeading、共通のコンテンツがある場合に使用。
（regionの要素が含まれる場合がある。）

IMDRF, RF

Headingが共通な場合に使用。コンテンツはregionの考慮が必要。

IMDRF (region) ：記載例、 IMDRF (USFDA, HC, JP)

すべての規制当局がHeadingを使用しているわけではない場合に使用。

Regional (region) ：記載例、 Regional (ANVISA, EU)

共通のコンテンツを含まない場合に使用。

ToC

RPSを本邦導入する場合に本邦の規制と整合されるようコンテンツ等を注視

ToC

CHAPTER 1 – REGIONAL ADMINISTRATIVE	
1.01	Cover Letter
1.02	Submission Table of Contents
1.03	List of Terms/Acronyms
1.04	Application Form/Administrative Information
1.05	Listing of Device(s)
1.06	Quality Management System, Full Quality System or Other Regulator
1.07	Free Sale Certificate/ Certificate of Marketing authorization
1.08	Expedited Review Documentation
1.09	User Fees
1.10	Pre-Submission Correspondence and Previous Regulator Interactions
1.11	Acceptance for Review Checklist
1.12	Statements/Certifications/Declarations of Conformity
1.12.01	Performance and Voluntary Standard
1.12.02	Environmental Assessment
1.12.03	Clinical Trial Certifications
1.12.04	Indications for Use Statement with Rx and/or OTC designation E

⊃

STED

製造販売承認申請書に添付すべき資料の項

添付資料	添付資料の項	
	局長通知（別表１）	STED 形式 （別添１及び別添２）
イ．開発の経緯及び外国における使用状況等に関する資料	１．開発の経緯に関する資料 ２．類似医療機器との比較 ３．外国における使用状況	１．品目の総括 １．１　品目の概要 １．２　開発の経緯 １．３　類似医療機器との比較 １．４　外国における使用状況 ３．機器に関する情報
ロ．設計及び開発に関する資料	１．性能及び安全性に関する資料 ２．その他設計検証に関する資料	４．設計検証及び妥当性確認文書の概要
ハ．法第 41 条第３項に規定する基準への適合性に関する資料	１．基本要件基準への適合宣言に関する資料 ２．基本要件基準への適合に関する資料	２．基本要件基準への適合性

outline

1.ToC

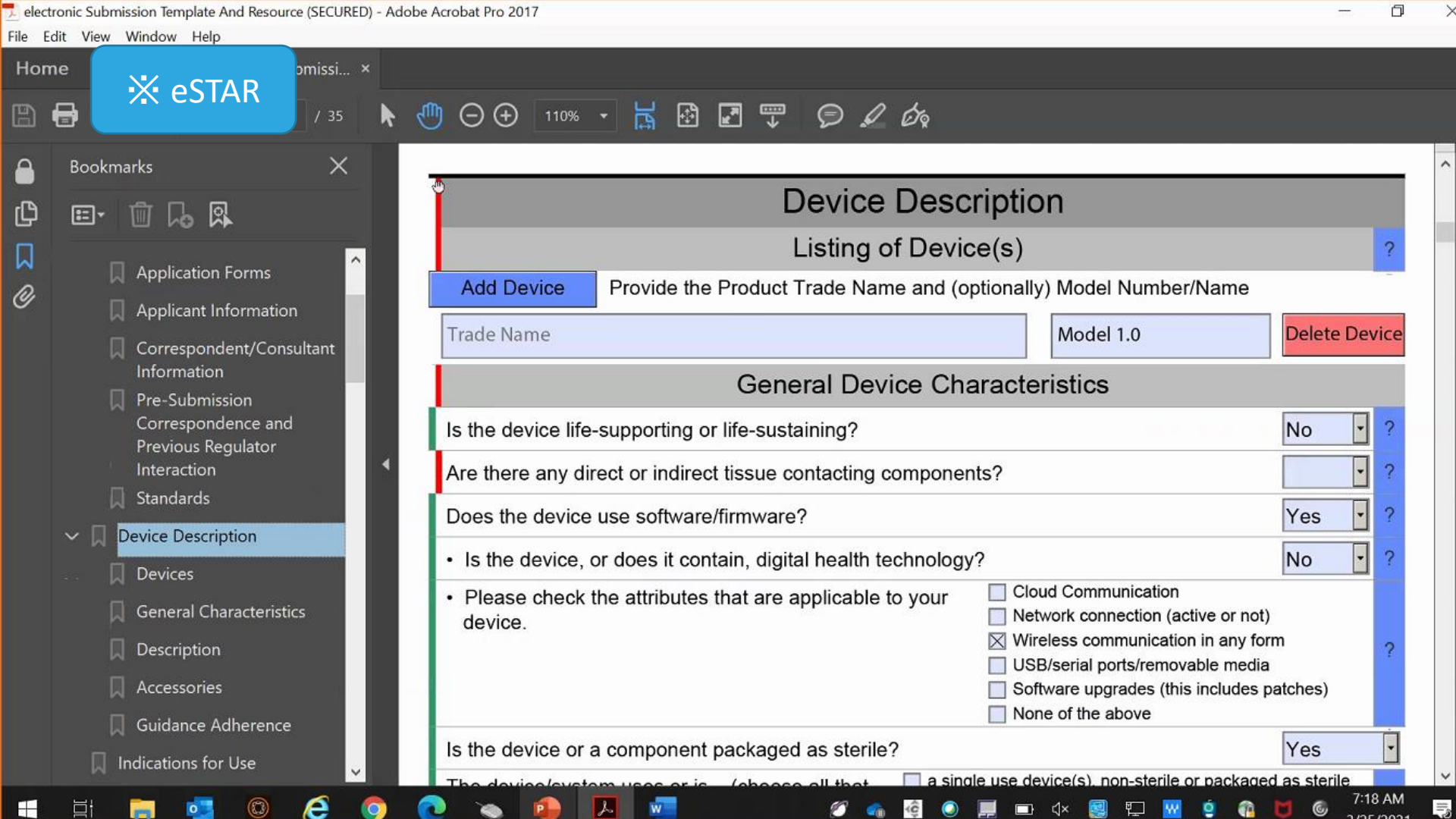
2.Dynamic Formatの開発

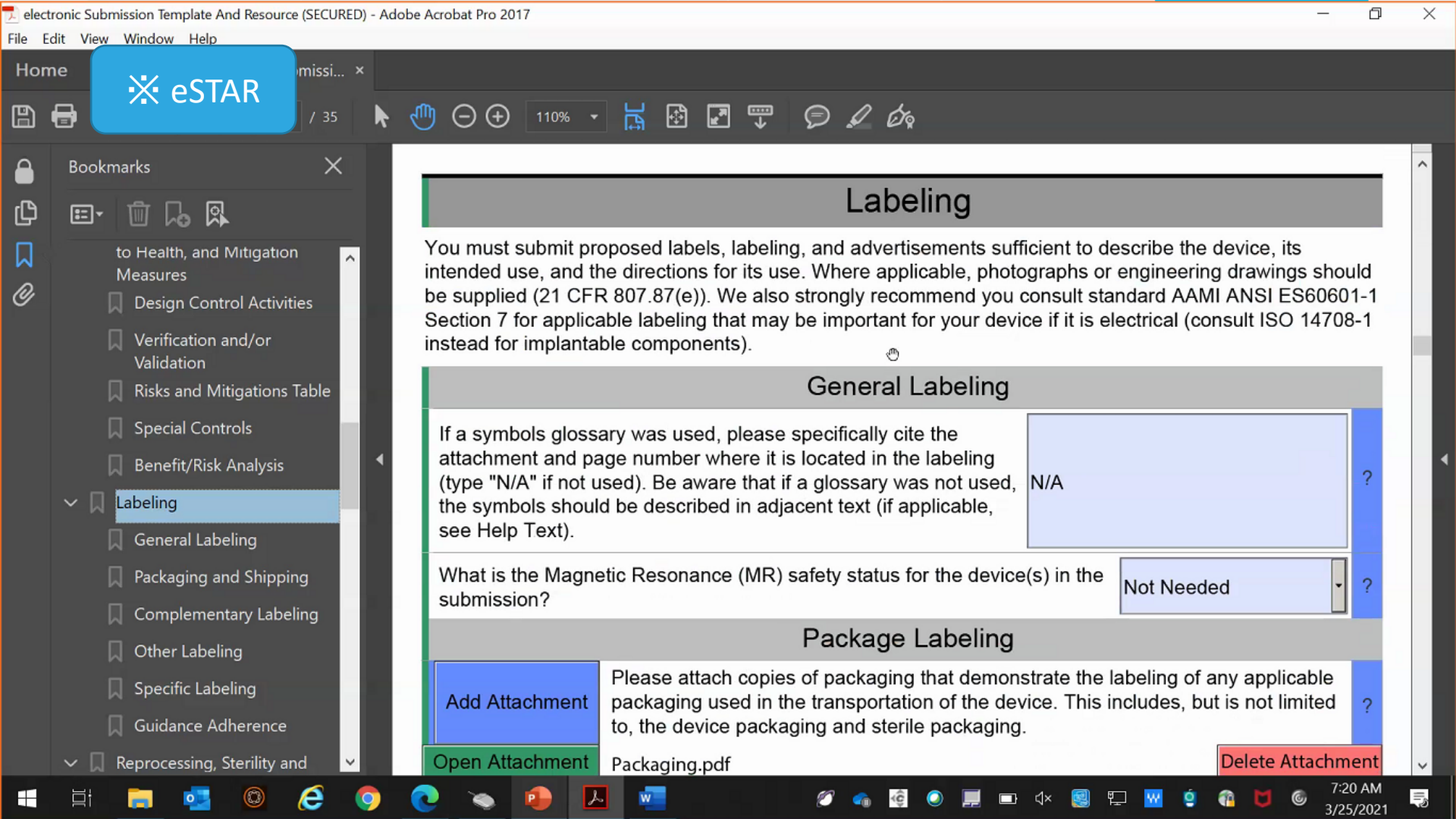
Dynamic Template

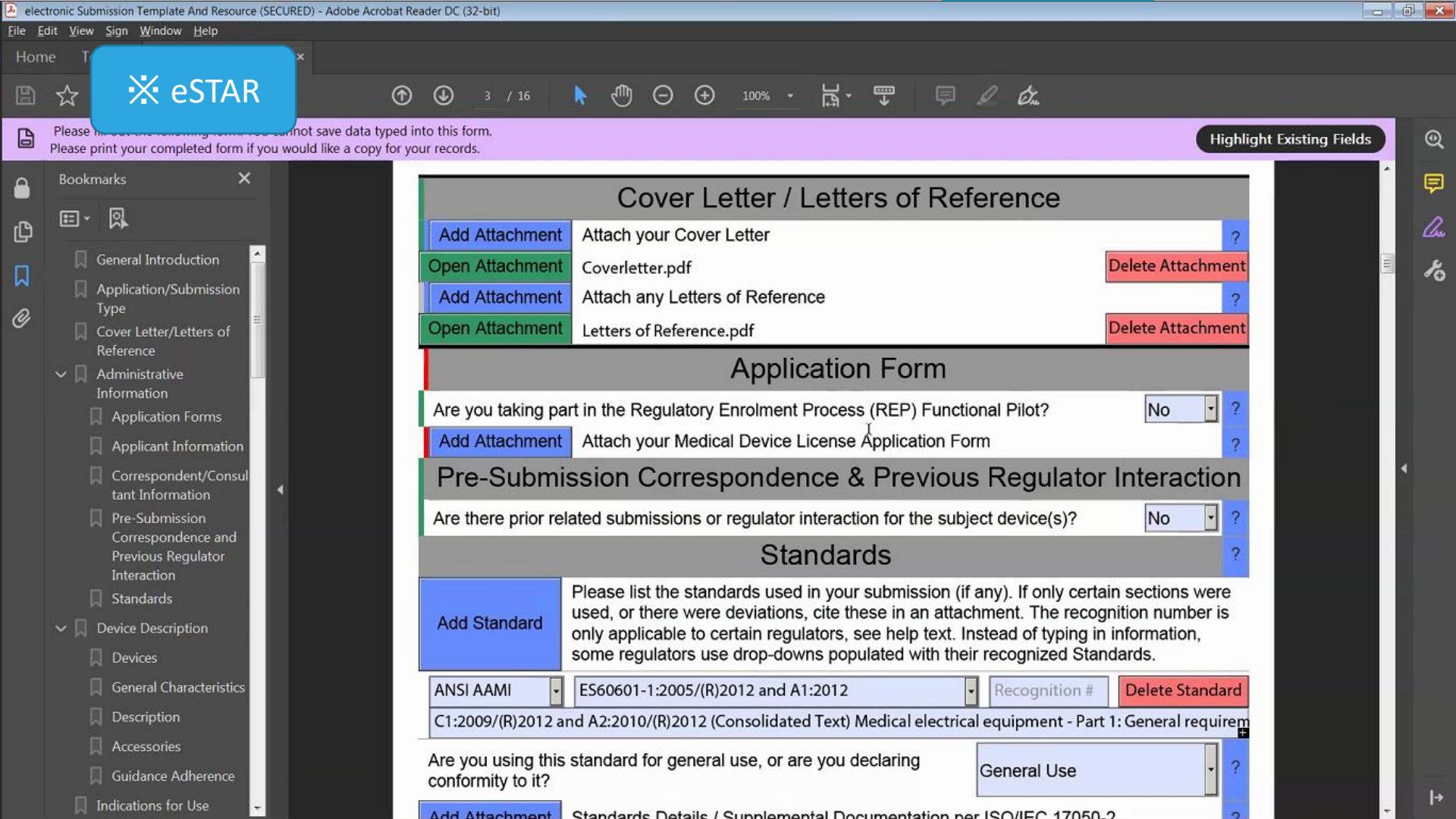
- 2021年3月に新規作業項目として承認
- FDAが採用しているeSTAR（*）と呼ばれる方式を参考に、PDFに直接必要事項等を入力して申請するためのテンプレートの作成を検討

  * The electronic Submission Template And Resource
- 手始めにToCの見直し・確認を行う予定

RPSを本邦導入する場合に本邦の規制と整合されるようコンテンツ等を注視


electronic Submission Template And Resource (SECURED) - Adobe Acrobat Pro 2017
File Edit View Window Help
Home
eSTAR
Bookmarks
Application Forms
Applicant Information
Correspondent/Consultant Information
Pre-Submission Correspondence and Previous Regulator Interaction
Standards
Device Description
Devices
General Characteristics
Description
Accessories
Guidance Adherence
Indications for Use
Device Description
Listing of Device(s)
Add Device
Provide the Product Trade Name and (optionally) Model Number/Name
Trade Name
Model 1.0
Delete Device
General Device Characteristics
Is the device life-supporting or life-sustaining?
No
Are there any direct or indirect tissue contacting components?
Does the device use software/firmware?
Yes
• Is the device, or does it contain, digital health technology?
No
• Please check the attributes that are applicable to your device.
Cloud Communication
Network connection (active or not)
Wireless communication in any form
USB/serial ports/removable media
Software upgrades (this includes patches)
None of the above
Is the device or a component packaged as sterile?
Yes
7:18 AM


electronic Submission Template And Resource (SECURED) - Adobe Acrobat Pro 2017
File Edit View Window Help
eSTAR
Home
Bookmarks
to Health, and Mitigation Measures
Design Control Activities
Verification and/or Validation
Risks and Mitigations Table
Special Controls
Benefit/Risk Analysis
Labeling
General Labeling
Packaging and Shipping
Complementary Labeling
Other Labeling
Specific Labeling
Guidance Adherence
Reprocessing, Sterility and
Labeling
You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).
General Labeling
If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).
N/A
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?
Not Needed
Package Labeling
Add Attachment
Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.
Open Attachment
Packaging.pdf
Delete Attachment
7:20 AM
3/25/2021


electronic Submission Template And Resource (SECURED) - Adobe Acrobat Reader DC (32-bit)
File Edit View Sign Window Help
Home
eSTAR
3 / 16
100%
Please print your completed form if you would like a copy for your records.
Highlight Existing Fields
Bookmarks
General Introduction
Application/Submission Type
Cover Letter/Letters of Reference
Administrative Information
Application Forms
Applicant Information
Correspondent/Consultant Information
Pre-Submission Correspondence and Previous Regulator Interaction
Standards
Device Description
Devices
General Characteristics
Description
Accessories
Guidance Adherence
Indications for Use
Cover Letter / Letters of Reference
Add Attachment
Attach your Cover Letter
Open Attachment
Coverletter.pdf
Delete Attachment
Add Attachment
Attach any Letters of Reference
Open Attachment
Letters of Reference.pdf
Delete Attachment
Application Form
Are you taking part in the Regulatory Enrolment Process (REP) Functional Pilot?
No
Add Attachment
Attach your Medical Device License Application Form
Pre-Submission Correspondence & Previous Regulator Interaction
Are there prior related submissions or regulator interaction for the subject device(s)?
No
Standards
Add Standard
Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.
ANSI AAMI
ES60601-1:2005/(R)2012 and A1:2012
Recognition #
Delete Standard
C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirem
Are you using this standard for general use, or are you declaring conformity to it?
General Use

まとめ

- RPSは、医療機器の電子申請に関する標準仕様の構築を目的した活動である。

- 機器の情報や臨床試験成績などの申請資料を構成する項目（ToC）に関するガイダンスやToCを用いた電子申請に関するガイダンスなどが作成された。
- また、パイロット版の試験が実施されている。

- 各国・地域の申請に対応可能なテンプレート（Dynamic Template）の作成に向けた検討が始まった。

- 本邦にRPSが導入された場合に、本邦の申請に内容と整合が取れるよう注視していく。

ご清聴ありがとうございました