European Federation of Pharmaceutical Industries and Associations

Topics Raised by EFPIA

Webinar on Policy 70

29 Jun 2017, FINAL






Presentation

Topics to discuss

- **Definition of listings out of scope of Phase 1**
  - Examples
- **Previously submitted studies in scope**
- **Reiterating EFPIA's concern**
  - Example
- **Processing of information in foreign language**
  - Suggestion
- **AOB**

Seeking practical and administrative clarity around Listings (Page 1 of 2)

- **We have experienced significant confusion and rework in the space of selecting the right listings to anonymize vs. remove, and how to format correctly**
  - Guidance version 2.0 on scope and format seeks to be based on location rather than type of listing
    - *Across the industry, CSR formation and listing location will continue to vary*

<u>Consider the types of Listings (Non-Comprehensive)</u>

- Safety Listings: All AEs, Drug-related AEs, AEs by subgroups (age, race, etc.), Serious AEs, Deaths, Discontinuations due to AEs, Substantially abnormal labs, All labs
- Efficacy Listings
- Baseline/Demographic Listings
- Accrual/Subject Status Listings
- Listing of Dosing Information
- Listing of Concomitant Medications
- Listing of Pretreatment Information (prior surgery/therapy, medical history, etc)
- Listing of Pharmacokinetic Information
- Listing of Quality of Life Measures

Seeking practical and administrative clarity around Listings (Page 2 of 2)

Examples:

1. Listing of specific AEs considered out of scope in a CSR when in Section 16.2. However, the same (pooled) listing is in scope when an appendix to an SCS
2. Regarding abnormal lab value lists from version 2: does the new rule mean that in the future ALL non-lab listings are in scope, even those in Section 16.2?
3. How is a “per patient per visit” listing defined? AE listing typically not by visit, but by date.
4. If a listing in question is in section 16, can it be removed without an overlay vs. if it’s in section 14, the overlay and reference to being out of scope.
5. Page numbers, are they required or not?

PROPOSED APPROACH:

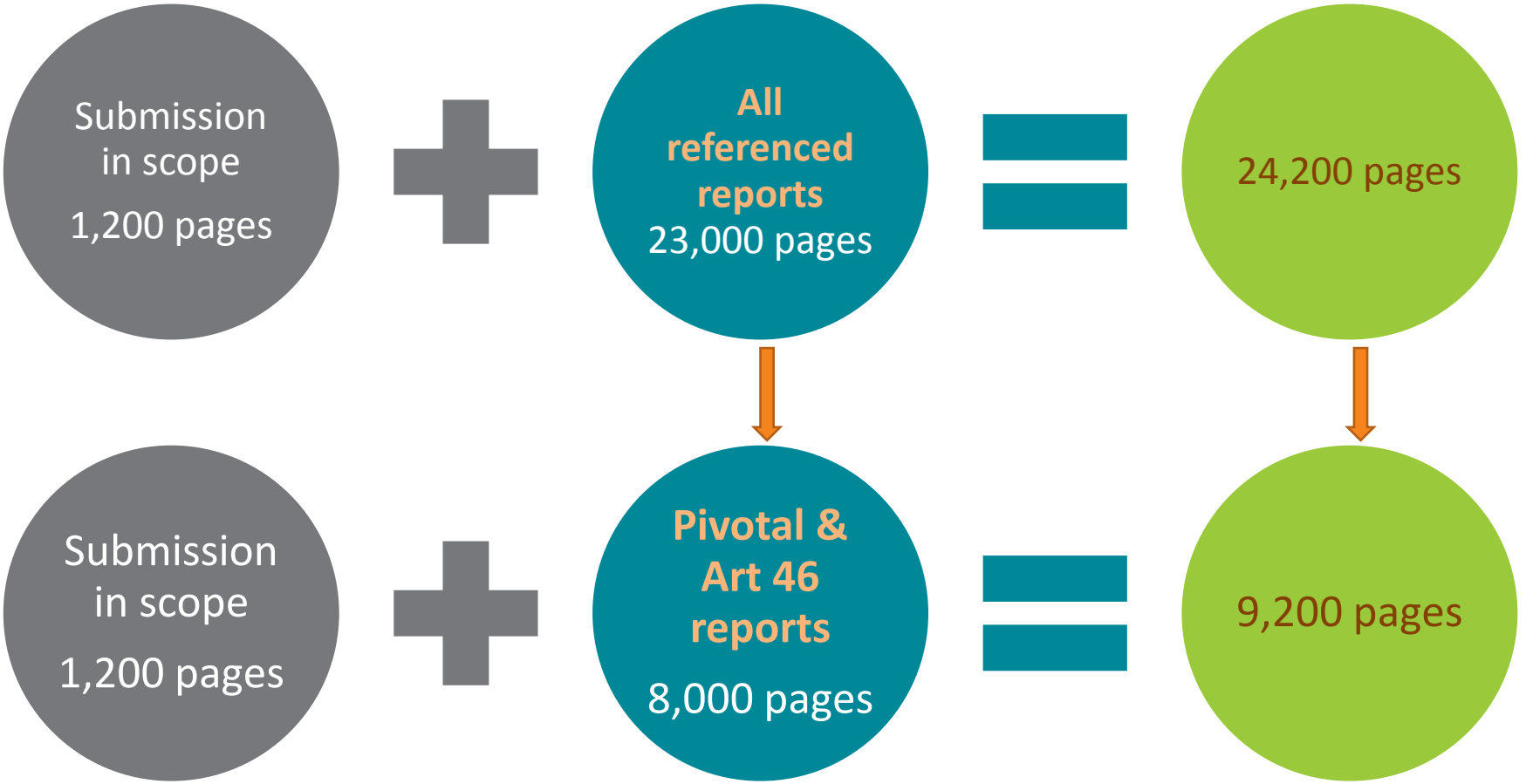
- Identify which listing types may be Anonymized vs. Removed in updated guidance based on type of listing, not location.
- Clarify when to Remove pages without overlay and when to apply the “out of scope of phase 1 ….” overlay.
- Industry would appreciate the opportunity to collaborate on this clarification

Previously submitted studies in scope

- **Acknowledge EMA has taken note of industry's request to revise its guidance regarding clinical reports submitted as part of regulatory procedures not falling within the scope of Policy 0070**
- **EFPIA is concerned that specific guidance relating to paediatric indications represents a significant and unnecessary extension to the scope of Policy 70.**
- **No clear rationale why paediatric and non-paediatric application should be treated differently**
- **PROPOSED APPROACH: Revise guidance (see EFPIA letter, 1 May 2017)**
  - **The following cross-referred clinical study reports will be subject to publication:**
    - Pivotal clinical study reports from procedures not falling within scope of Policy 0070 and considered basis for paediatric application
    - Clinical study reports submitted under Article 46

Previously submitted studies in scope:

Example: Scope for Pediatric Submission (clinical reports, excl summaries)



Previously submitted studies in scope:

Example: Paediatric variation submission of a combination product (A+B)

	Section	Description/Leaf title of trials cross-referenced in submission	Considered in scope for Policy 0070	Comment
1	5.3.1	Paediatric trial in compound (A+B)	Yes	Pivotal paediatric study for the combination product
2	5.3.1	Supportive (2 parts) – phase 3 - compound A only – In paediatrics	Yes	Supportive study documenting effect in one of the medicinal products, not the combination product itself
3	5.3.1	Supportive - phase 1 – compound A only – In paediatrics	Yes	Supportive study documenting effect in one of the medicinal products, not the combination product itself
4	5.3.1	Supportive – phase 1 – Compound A+B – In paediatrics	Yes	Supportive study investigating the pharmacokinetics of the combination product
5	5.3.1	Supportive (2 parts) – phase 3 – compound A+B - In adults	No	Supportive study in adults, investigating the long-term safety and tolerability of the combination product
6	5.3.5.4	Supportive - Modelling report for compound A+B	Yes	Modelling report based on above study data, does not contain any new clinical data

How to deal with Non-English content

- **Two scenarios exist which require clear rules of engagement:**
  - Scenario 1: Pages in Non-English without equivalent pages in English
  - Scenario 2: Pages in Non-English with an English equivalent

- **Examples:**

1. Chinese Autopsy – non English version NOT available
2. eCRF in French – English version is included

PROPOSED APPROACH:

Scenario 1:

- Remove Non-English pages
- Insert overlay that removed due to being in non-English language without an English translation being available (to ensure protection of local patients)

Scenario 2:

- Remove Non-English pages
- No overlay is inserted because same content is already included

AOB

- **Reiterating the benefits to EMA and Industry to good control in guideline changes**
  - Tools
  - Processes, SOPs,
  - Consistent expectations of submitters and reviewers

- **Ensuring the intended implementation of processing cover letter and reference to out of scope parts:**
  - Which sections should be included – only those non-standard removed where an overlay is inserted, or all sections even those clearly in out of scope sections such as section 16?
  - Can we have an example or template for this in the cover letter?