SBIA-DMF Drug substance workshop

March 3 & 4, 2021 (Virtual)

Metrics on DMF Assessments – Productivity, Output, and Metrics
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Division of Life Sciences API
March 3 & 4, 2021
Virtual

PURPOSE

The purpose of this poster is to present the Productivity, Output and Metrics on the performance of the Assessors in the Office of New Drug Products/Division of Lifecycle API.

OBJECTIVE(S)

To assess the total number of API Assessments completed in 2020 and present the results in terms of type of assessment, assessment time, and assessment result.

METHOD(S)

All DMF Original submissions and amendments assessed are tracked by date of completion, assessment result and time spent on assessment. The data is compiled and graphed to show the metrics on the review process.

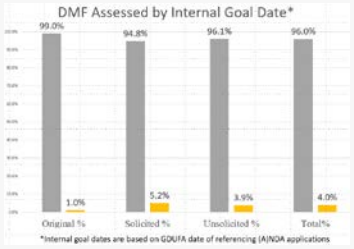
TYPES OF DMF SUBMISSIONS

Original Submissions

Amendments

- **Solicited (Amendments submitted in response to assessment deficiencies)**
- **Unsolicited (Amendment submitted by the firm for updates/changes to the DMF)**

RESULT(S)



Timely Completion

From the data gathered from the assessors, over 95% of all DMF assessments are completed by the internal goal date. For the assessments not completed by the goal date, the major reasons are as follows:

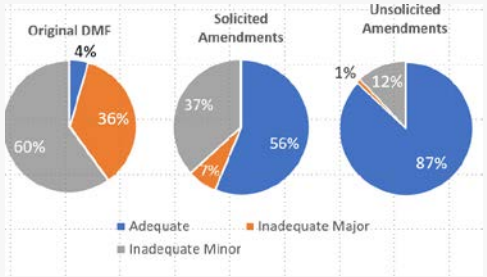
- Late cycle submission of amendments to a DMF
- Incomplete information on potential genotoxic compounds

Assessment Outcomes

Originals

Based on the assessments, the majority of the original DMF submissions are inadequate in the first review cycle. The reasons for the inadequacy are typically as follows:

- Control strategy for potential genotoxic compounds
- Incomplete information and/or validation of analytical methods
- Incomplete description of process steps, critical control parameters and in-process controls



Solicited Amendments

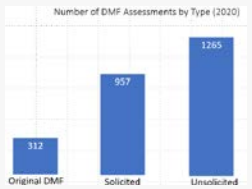
Over half of the responses to deficiencies are adequate. The reasons for inadequacy are incomplete or inadequate responses to the deficiencies.

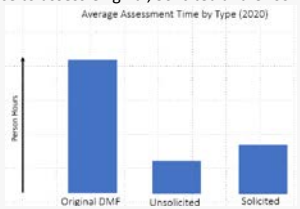
Unsolicited Amendments

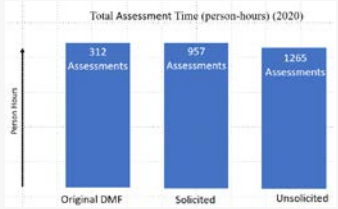
The majority of the unsolicited amendments are adequate in the first assessment cycle.

Assessment times

An original DMF requires the most assessment time; based on the total number of each type of amendment received and the complexity of the assessment, the Division expends about equal resource to assess Original, Solicited and Unsolicited submissions.







CONCLUSION(S)

The Division completes 2500-3000 DMF assessments per year. Over 95% of the assessment are completed by the internal goal date which assists in a completion assessment of referencing (A)NDA applications reviewed at >90% meeting GDUFA target dates.

The majority (2/3) of all DMF originals and amendments are found adequate although improvement in submission quality could raise this number significantly, especially for original reviews.

Individual assessments take more time for original assessments, compared to assessment of solicited and unsolicited amendments. Based on the total numbers of each type of assessment, the division spends roughly an equal amount of effort on each type of assessment (Original, Solicited and unsolicited).

Based on the information obtained from this study, on-going efforts will be made to increase assessor efficiency and provide feedback to submitters on DMF's on how to maximize the quality of their submissions.

One-Third of the Division's capacity is spent for assessment of DMF responses to deficiencies.

Fewer first cycle deficiencies and more adequate responses to deficiencies can lead to a faster assessment time and greater assessment capacity and for the Division

DMF Assessments
Productivity, Output, and Metrics

Steven Kinsley and Wei Song

-Type and number of Assessments

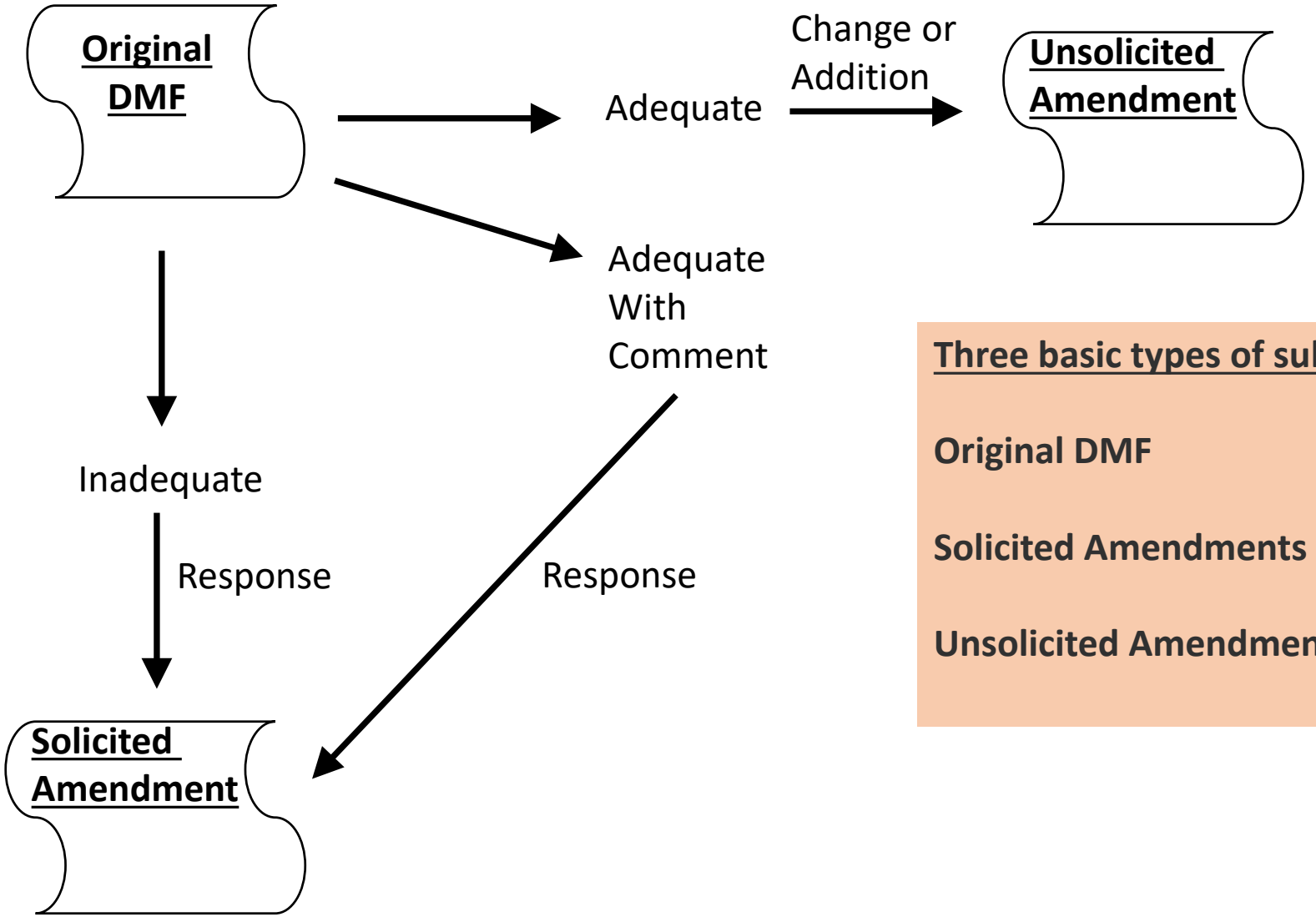
-Meeting of Assessment Goal Dates

-Person Hours Required for Assessments

-Assessment Outcomes

-Conclusions and Recommendations

Types of Submissions Assessed for Drug Master Files



Three basic types of submissions

Original DMF

Solicited Amendments

Unsolicited Amendments

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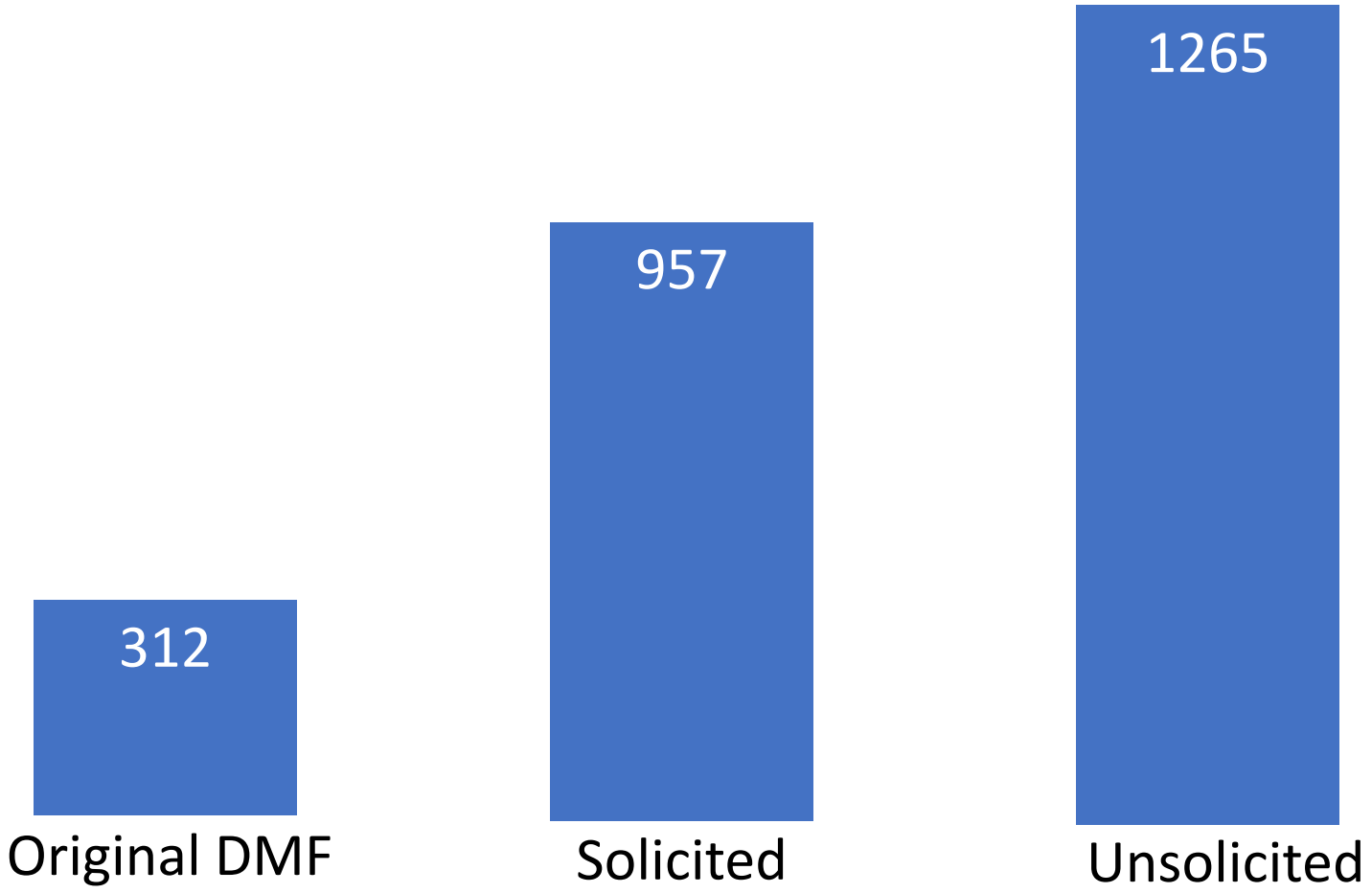
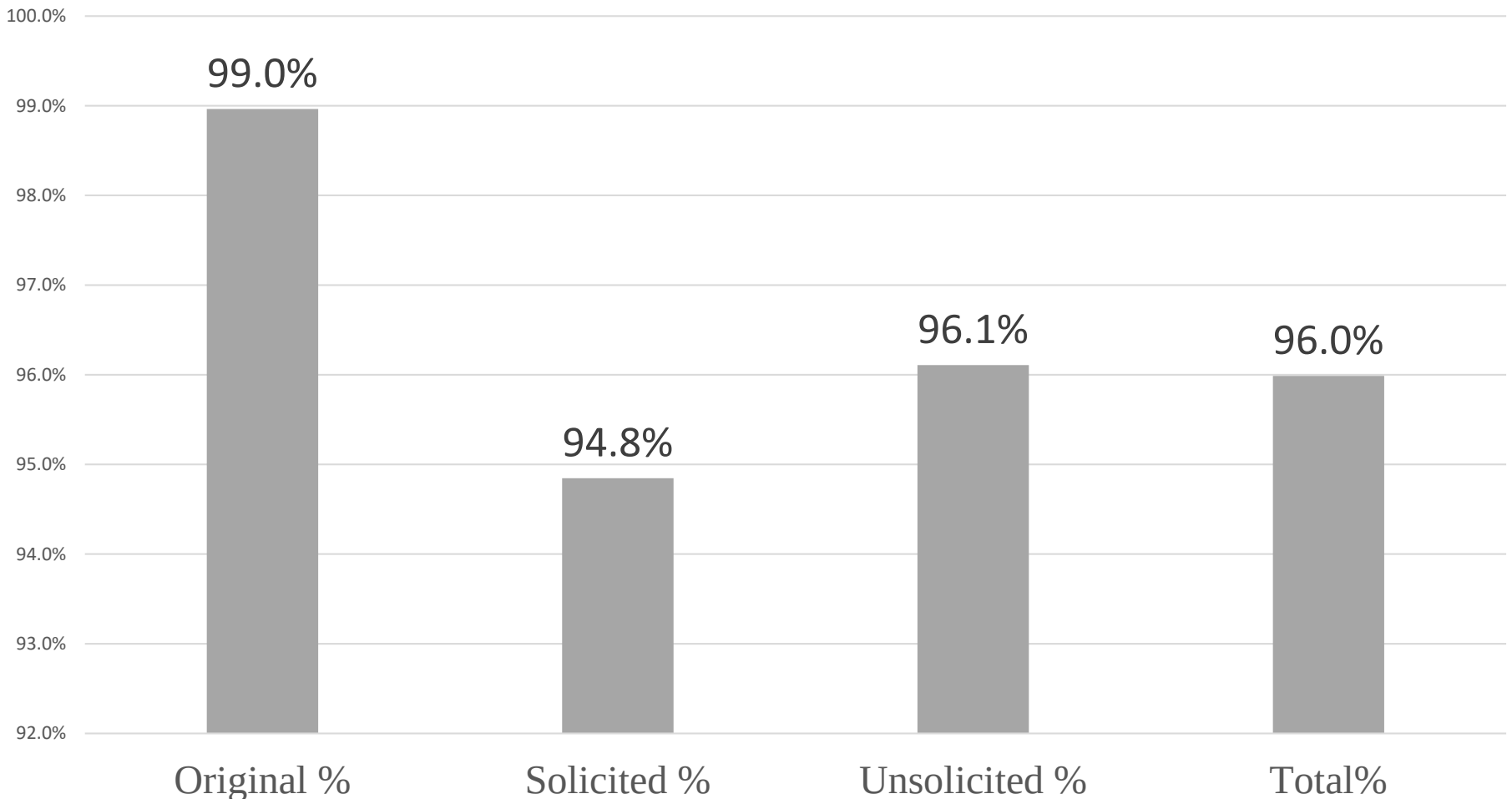
Number of DMF Assessments by Type (2020)



In an average year, the Division Completes 2500-3000 Assessments

Over 2500 assessments were completed by the Division in 2020.

DMF Assessed by Internal Goal Date*



*Internal goal dates are based on GDUFA date of referencing (A)NDA applications

Over 95% of the Division's assessments are completed on or before our internal goal dates.

This results in over 90% of applications meeting the GDUFA target goal dates.

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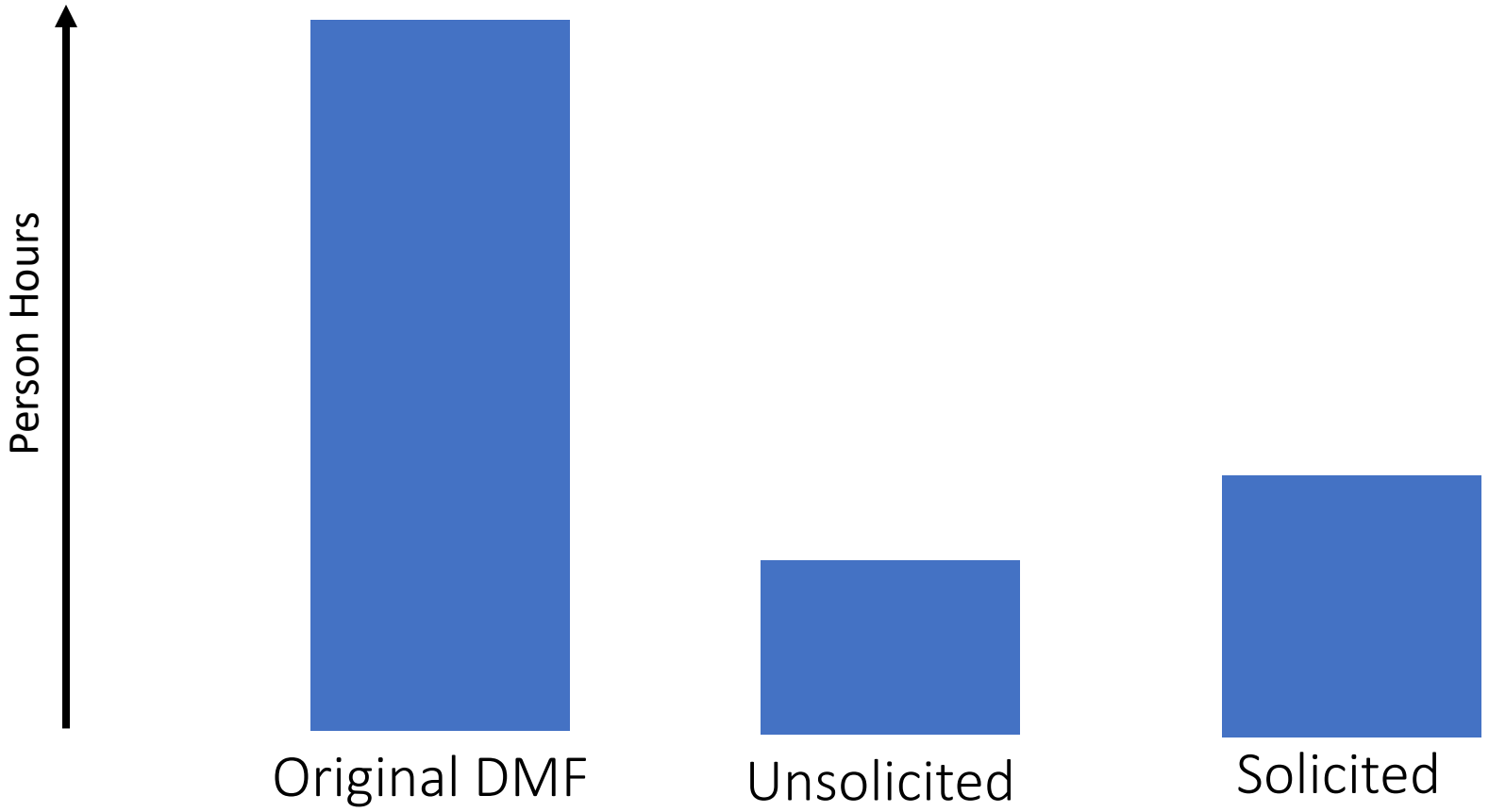
Average Assessment Time by Type (2020)



On Average, it takes more time to assess an Original DMF than amendments.

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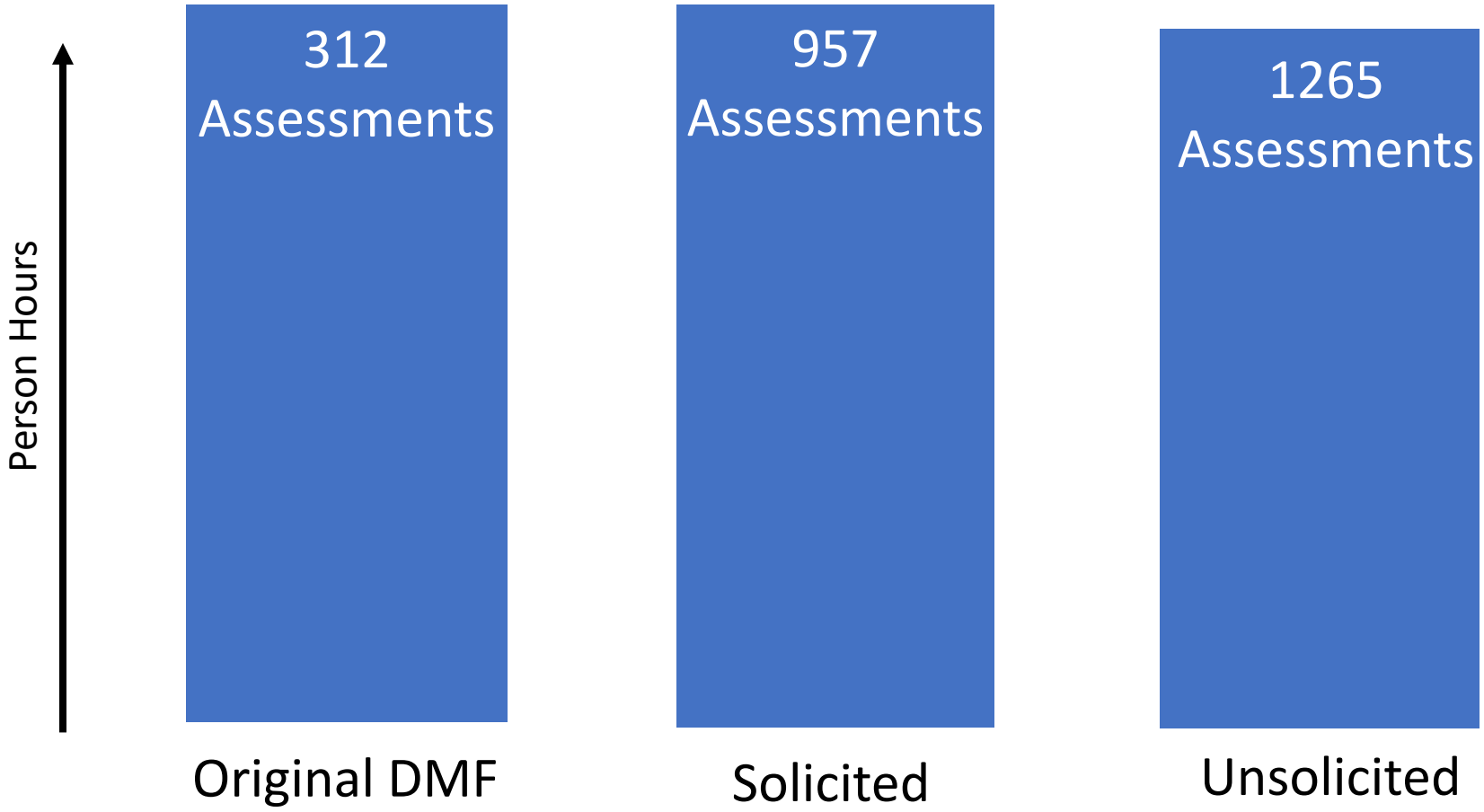
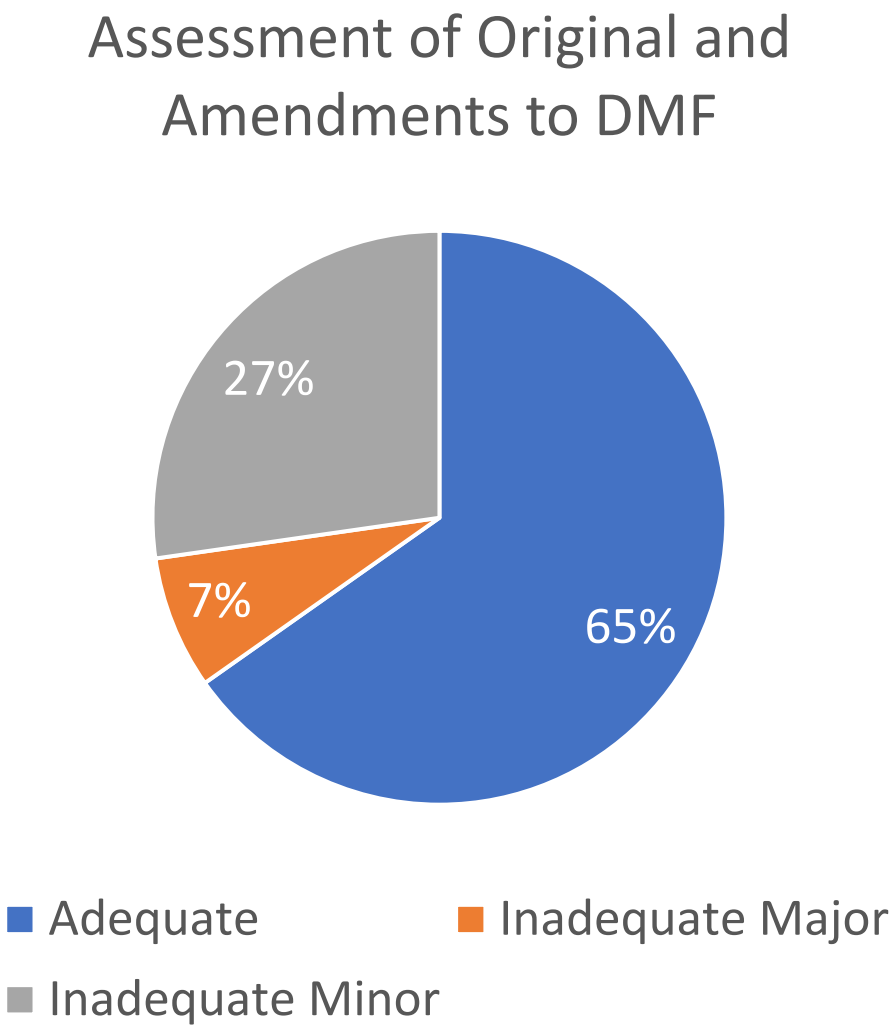
Total Assessment Time (person-hours) (2020)

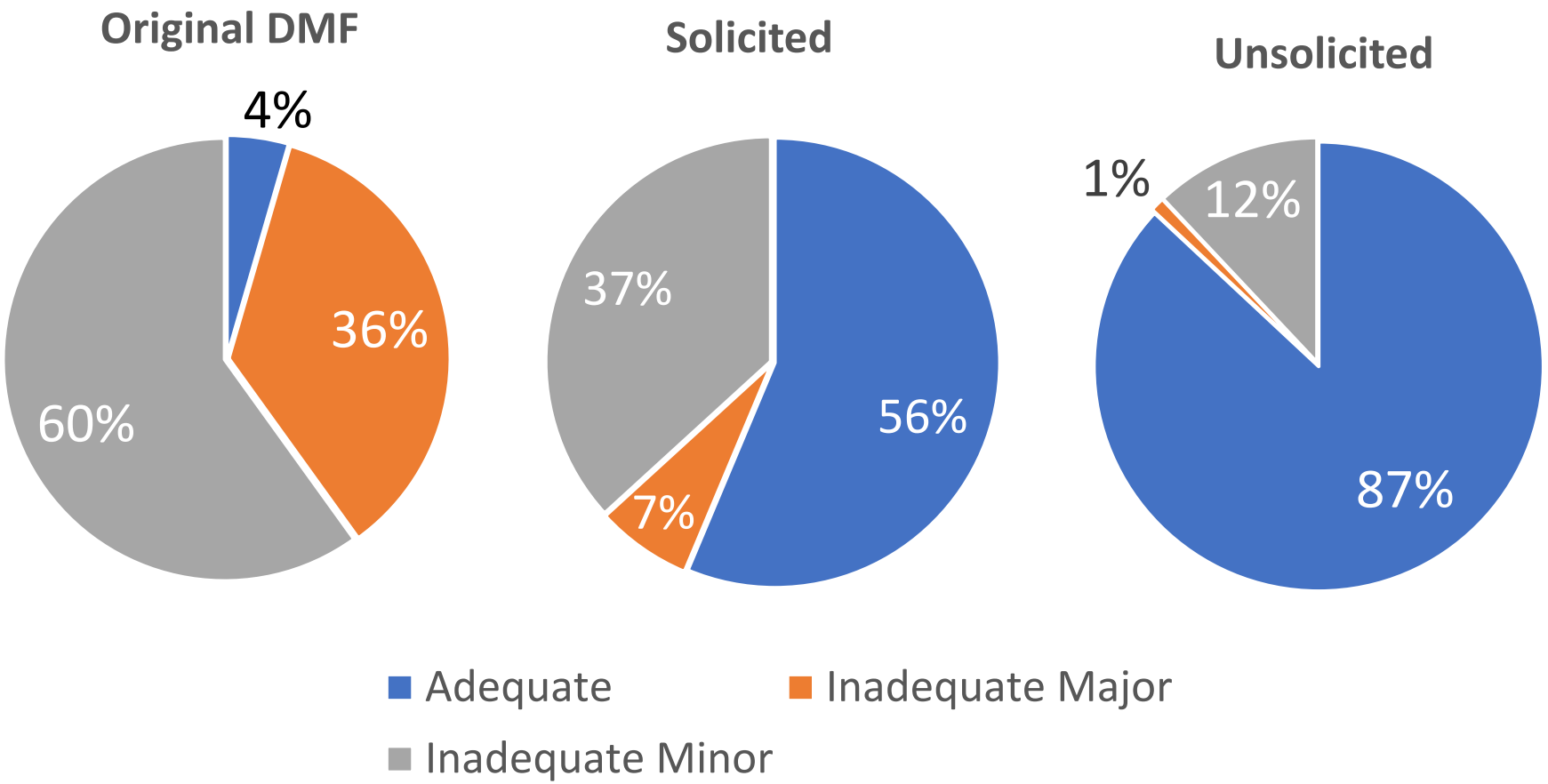


Based on the number of originals and amendments, the number of person hours used to assess Original, Solicited and Unsolicited amendments are about the same.



The majority of submissions (Originals and amendments) are assessed as adequate to support the referencing application.

Review Assessment by Submission Type and Outcome



Currently, the majority of Original DMF submissions are not assessed as adequate in the first cycle.

Almost half of the responses to deficiencies are not assessed as adequate.

Observations and Recommendations

1. The Division of Life Cycle API performs about 2500-3000 assessments per year.

2. About 10% of the assessments are for Original DMFs.

3. One-Third of the Division's capacity is spent for assessment of DMF responses to deficiencies.

4. **Fewer first cycle deficiencies and more adequate responses to deficiencies can lead to a faster assessment time and greater assessment capacity and for the Division**.

Thank You!

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- Send questions regarding this poster to: DMFWorkshop2021@fda.hhs.gov by 2/15/2021 for inclusion in the poster Q&A session on *March3rd*

- Follow-on webinar for both posters/presentations on April 9, 2021. Questions can be sent to the above email by 3/19/2021 for the webinar.

- Please refer to the following presentations on March 3rd and 4th for additional information: *Effective Communication strategies For Drug Master Files (DMF); Common CMC Issues in Type II DMFs and How to Avoid Them.*