

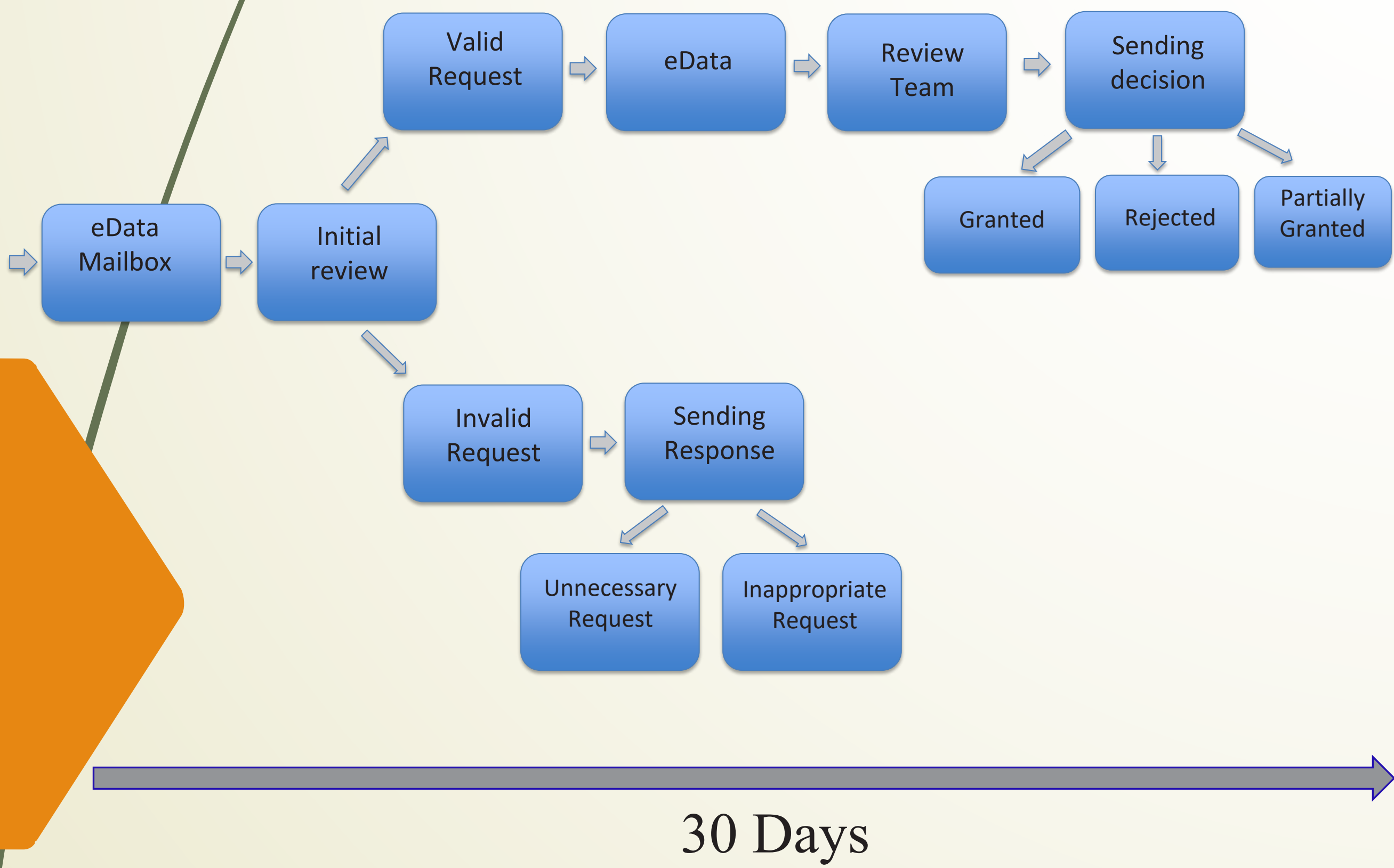
Two Types of Mistakes When Requesting Waiver to Current Supported Study Data Standard Versions

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Background

- Sponsors or applicants may apply for a waiver from the requirement to use **specific versions** of FDA-supported standards for the submission of study data
- Waiver to Current Supported Study Data Standard Versions can enable a sponsor to submit study data electronically using a version of a standard that was previously supported by FDA
- There is guidelines for requesting waiver to current supported study data standard versions - <https://www.fda.gov/drugs/forms-submission-requirements/guidelines-requesting-waiver-current-supported-study-data-standard-versions>
- CDER received waiver requests with mistakes.
- There are two types of common mistakes of submitting waiver requests.

Review Process of Waiver Request



Two Types of Mistakes of Submitting Waiver Request

1. Unnecessary Waiver Requests

Example of Mistake

- Study Start Date: Mar 1, 2010
- Data standard used: SDTMIG 3.1.1
- Date Support Ends for the standard: 1/28/2015
- Planned Submission Date: Oct 2020

Reason of the Mistake

Misunderstanding of what Date Support Ends refer to
Study Start Date vs Submission Date

2. Inappropriate Waiver Requests

Example of Mistake

- Study Start Date: Dec 20, 2017
- Requesting a waiver from the requirement of submitting standard data

Reason of the Mistake

- Misunderstanding the definition of waiver request.
- Data standard waiver requests are for requesting a waiver to current supported clinical study data standard **versions**, not for requesting a waiver from the requirement of submitting standard data for studies.

Statistics of Waiver Requests (2017 – 2023)

- Requests received in total: **50**
- Request Granted: **16, 32%**
- Partially Granted: **1, 2%**
- Request Rejected: **7, 14%**
- Unnecessary Requests: **18, 36%**
- Inappropriate requests: **7, 14%**

Summary

In summary, there are two types of mistakes when submitting waiver request to current Supported study data standard versions. The two types of mistakes are unnecessary waiver request and inappropriate waiver request. The reasons caused the mistakes are misunderstanding of what Date Support Ends refer to and misunderstanding the definition of waiver current Supported study data standard versions.

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