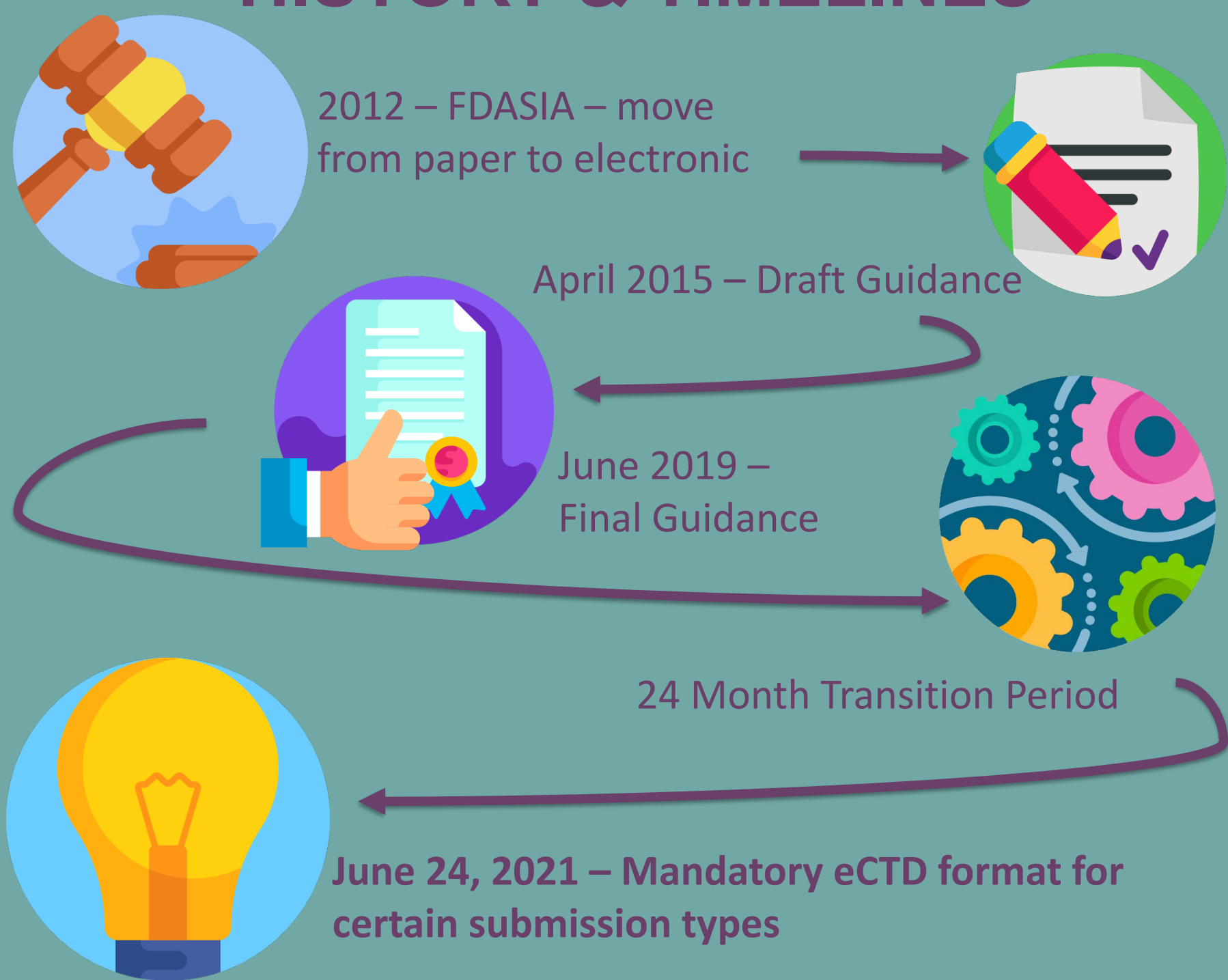


AD PROMO SUBMISSIONS

Preparing for the eCTD Mandate

HISTORY & TIMELINES



MANDATORY SUBMISSION TYPES

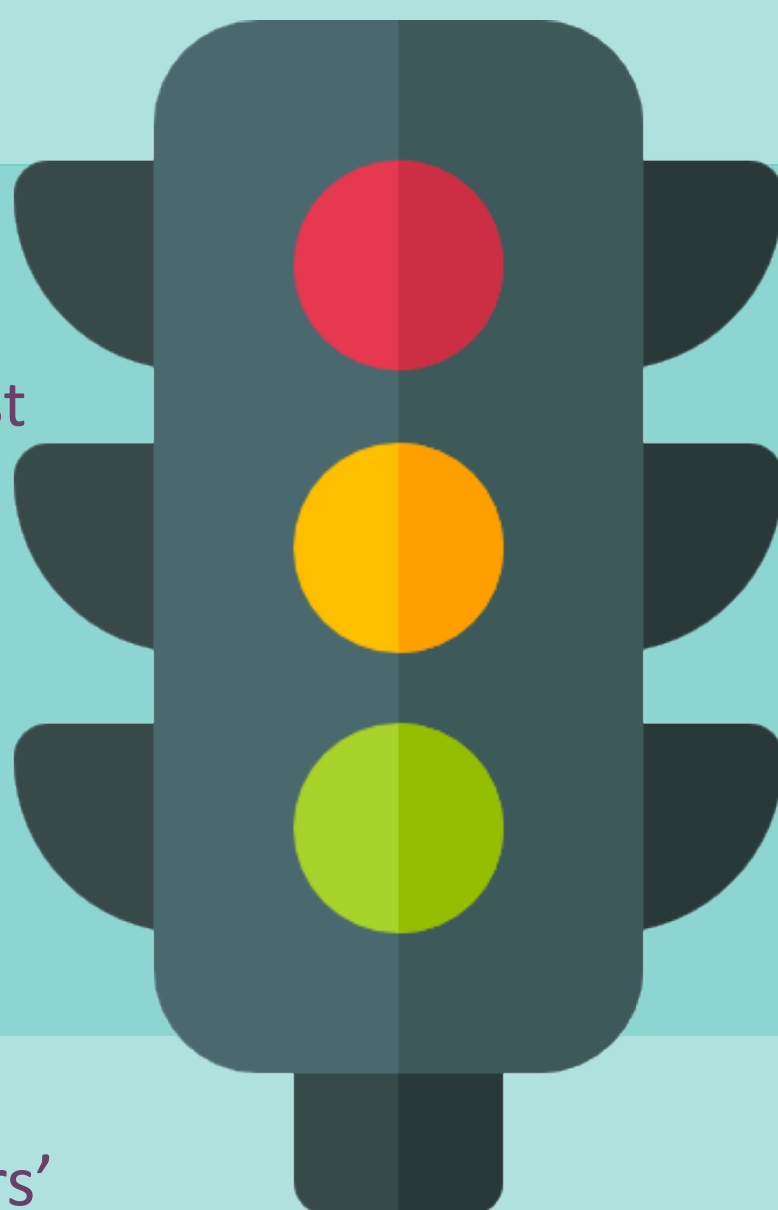
- 2253 Submissions
- Accelerated Approval Products

NON-MANDATORY ECTD

- General Correspondence
 - Response to information request
 - Resubmission of draft materials due to FDA comments
- Voluntary submission of draft materials
 - Core Materials & Non-core Materials
 - DTC TV Ads for review

NEVER ECTD

- Complaints about other sponsors' materials



2253 REQUIRED COMPONENTS

- FDA Form 2253
- Current Product Label
- Promotional Materials
- Promotional Materials (Annotated)

ACCELERATED APPROVAL PRODUCTS REQUIRED COMPONENTS

- Cover Letter
- Materials--
- Clean Version
- Annotated Version
- Annotated Labeling Version
- Annotated References

*CBER requires Form 2253



**THE CLOCK IS TICKING
JUNE 24, 2021**



For Ad Promo Submissions and all your Regulatory Operations and Submission Management needs, contact us today!

info@waysps.com or +1.484.352.3236

www.waysps.com