Navigating USFDA landscape

Periodic Safety Reports for Device Constituent Part

Overview of Combination Products

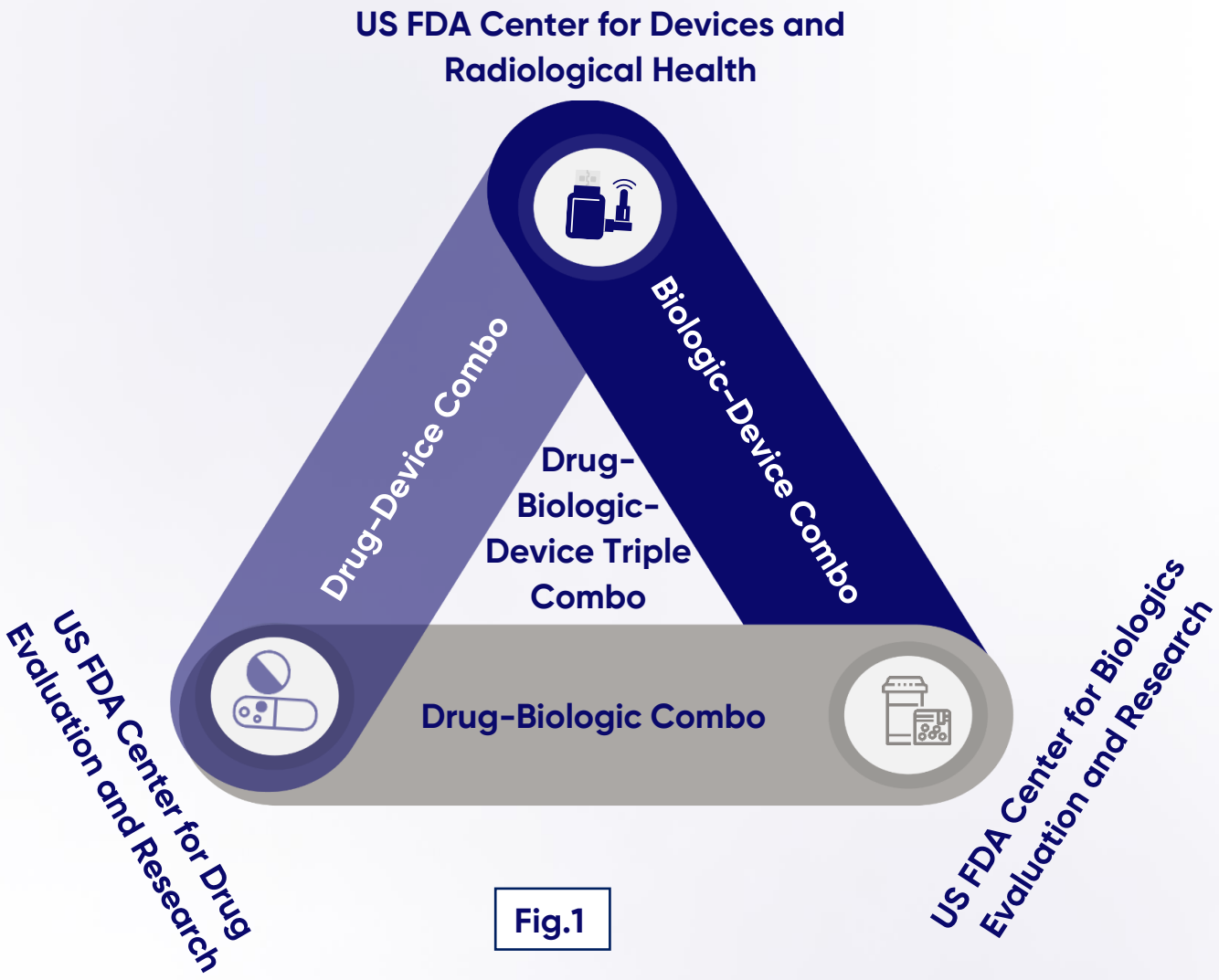


Fig.1

- A combination product is a product composed of any combination of a drug, a device, and a biological product.
- Each drug, device, and biological product included in a combination product is referred to as a "constituent part" of the combination product.
- Under section 503(g)(1) of the FD&C Act, assignment of a combination product to a lead Center is based on primary mode of action (PMOA) of the constituent product.

Safety Reporting Requirements for Combination Product or Constituent Part Applicant

- Combination Product Applicant are those that holds the only application or all applications for a combination product while Constituent Part Applicant are applicants that holds a license for a constituent part of a combination product.
- Both Combination Product and Constituent Part Applicants must meet the safety reporting requirements associated with the application type under which their combination product or constituent part received marketing authorization.
- In addition to application type-based reporting requirements, only Combination Product Applicants are also subject to certain safety reporting requirements associated with the constituent parts of the combination product (Refer below Fig-2)

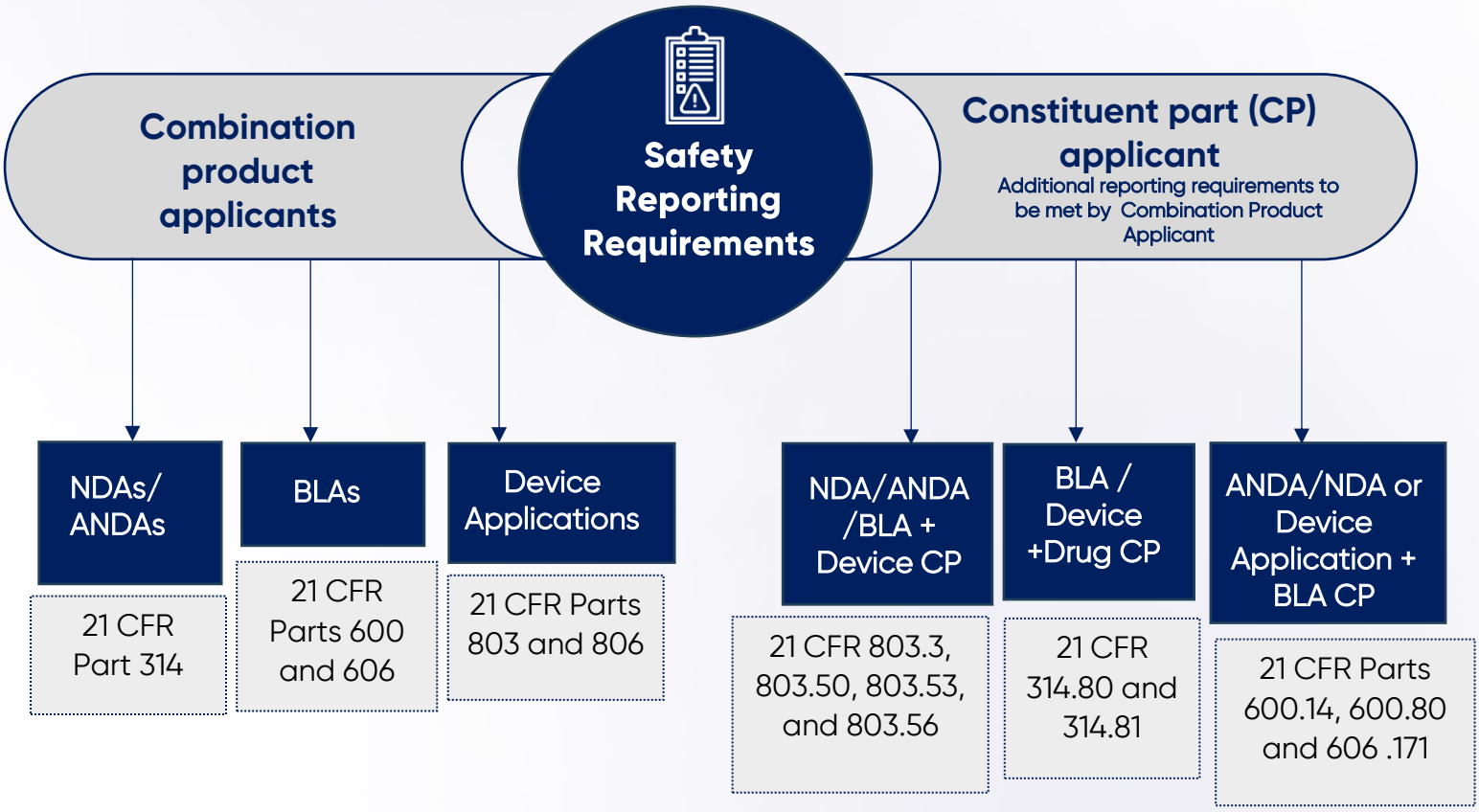
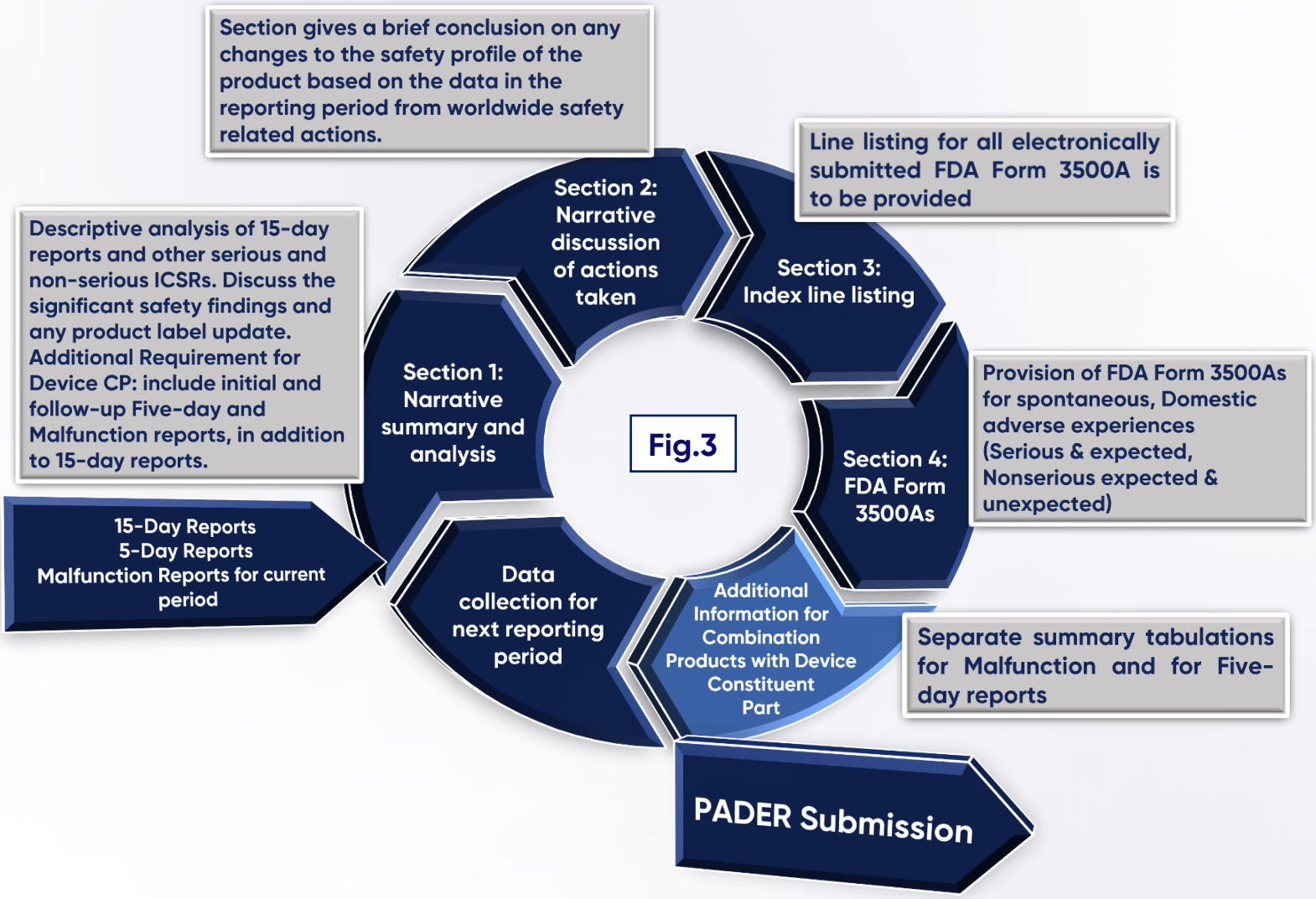


Fig.2

Glimpse of Periodic Reports



Glimpse of Summary Tabulation

Fig.4

- If an adverse event required both a Fifteen-day and Malfunction report, the event should also be included in the summary tabulations of adverse events.
- Separate summary tabulations for Malfunction and for Five-day reports is required, regardless of whether the malfunction or Five-day reportable action related to an adverse event.

Our Key Capabilities

Aggregate Reports

- PSUR / PBRER for Drugs, Biologics/Biosimilars,
- PSUR & PMSR for Devices
- PADER for Drugs, Biologics/Biosimilars, Combination products (Drug+ Device / BLA + Device)
- DSURs for Drugs, Biologics/Biosimilars
- ACOs/CES

Risk Management

- Core RMP, Developmental RMP
- Global RMP
- Local RMP including REMS
- RMM designing, Implementation strategy, RMM Tracking (aRMM TREX), Effectiveness assessment for RMMs
- Shared system REMS Support

Signal Management for Drugs, Biologics/Biosimilars

- Signal/ Trending Reports for Devices

Infinite Scientific Innovations

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