



Guidance Documents: OC Perspective

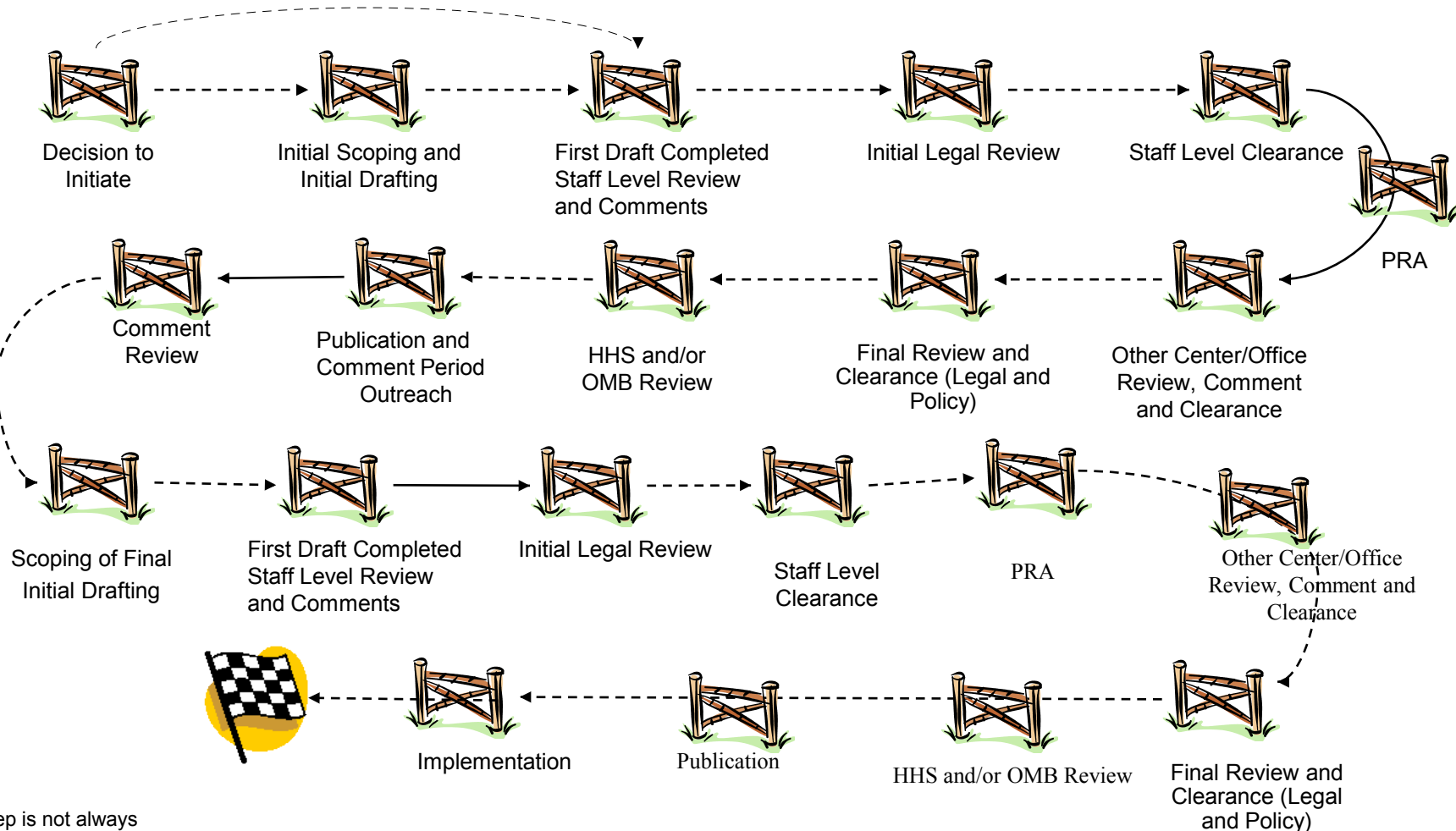
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FDA's Guidance Process

START TO FINISH*



*Each step is not always required and the order of steps may vary.

FDA Guidance Principles and Considerations

- Represents FDA's Official Position
- Important to FDA that guidance be:
 - Technically sound
 - Reliable
 - Useful
 - Consistent
 - With other Center guidance
 - Across FDA
 - Legally sound
 - Developed with stakeholder input

FDA Best Practices

- Initiation
- Prioritization
- Drafting
- FDA Clearance
- External Clearance
- Outreach
- Finalization
- Implementation

Challenges and Opportunities

- Stakeholder Engagement
- Draft to Final
- Priorities and Resources