EFFICIENT USE OF PREMARKET DATA SETS TO MEET BOTH FDA-CMS REQUIREMENTS

Daniel Arthur Caños CMS/CCSQ/CAG

CDRH's Expedited Access (EAP) PMA Program

- What is the role of adjudication in these situations to satisfy coverage with evidence development (CED) for CMS?

- In what cases could the additional effort needed for endpoint adjudication reduce the length or breadth of post-market follow-up

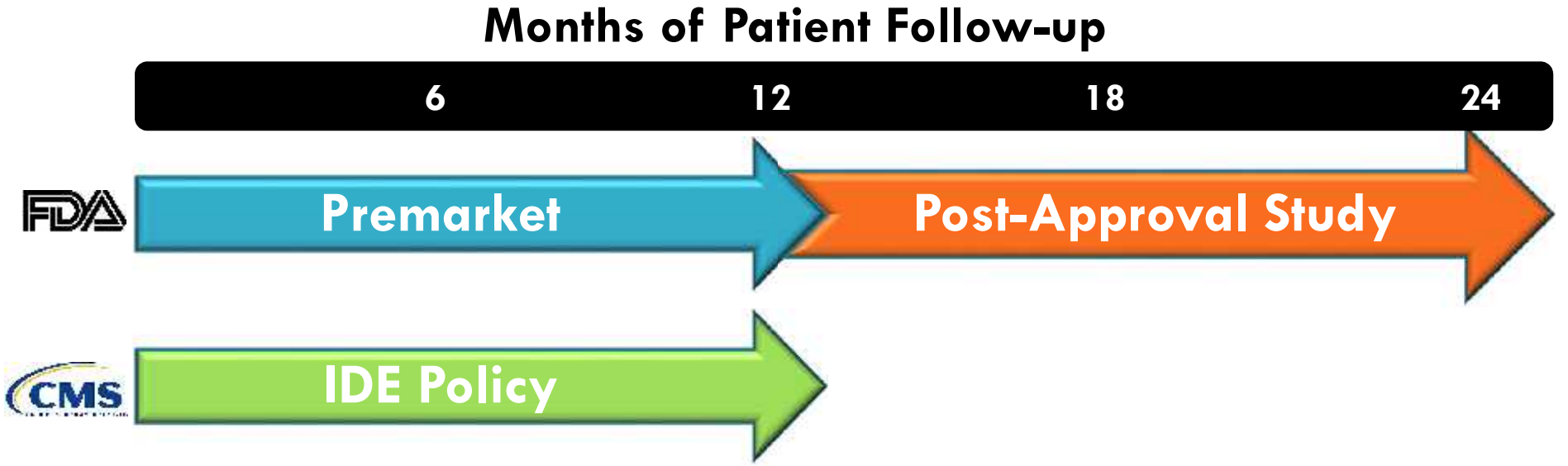
EAP Clinical Evidence That May Support Approval

1) Two-Phase Studies

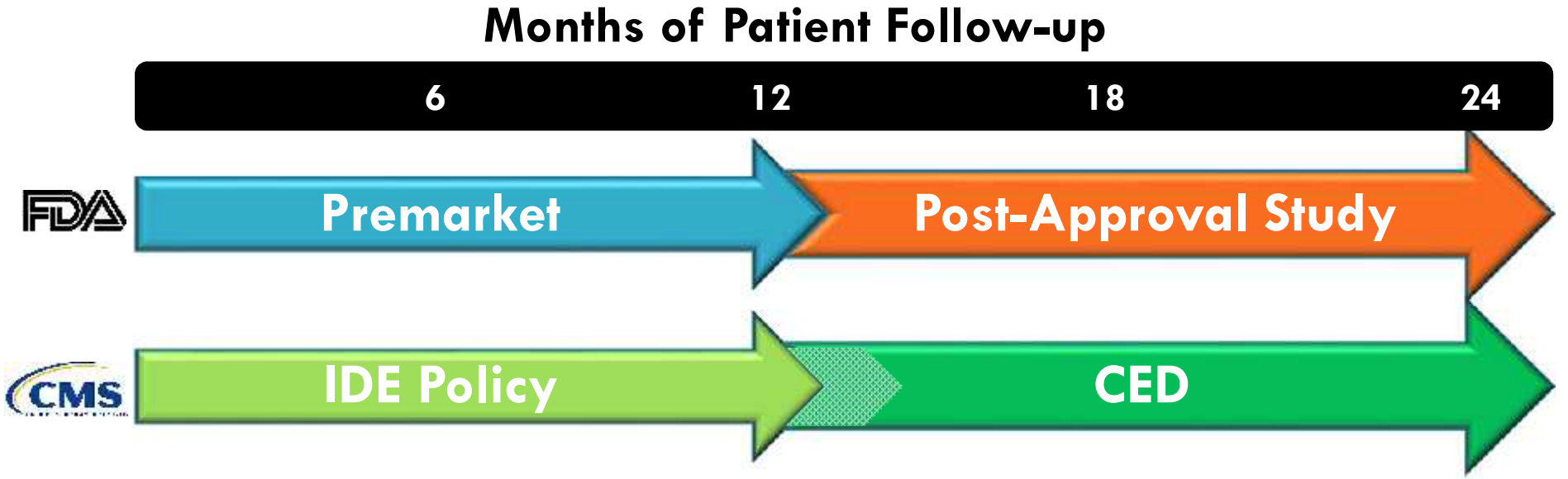
2) Intermediate and Surrogate Endpoints

3) In Vitro Diagnostics

Conventional Approvals



Conventional Approvals CMS CED



EAP Clinical Evidence That May Support Approval

1) Two-Phase Studies

   - What is the role of adjudication in these situations to satisfy coverage with evidence development (CED) for CMS?

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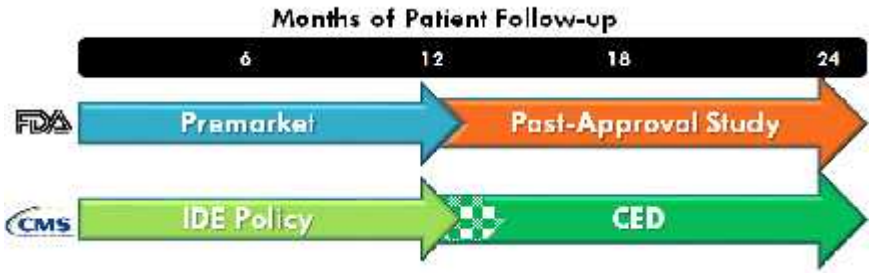
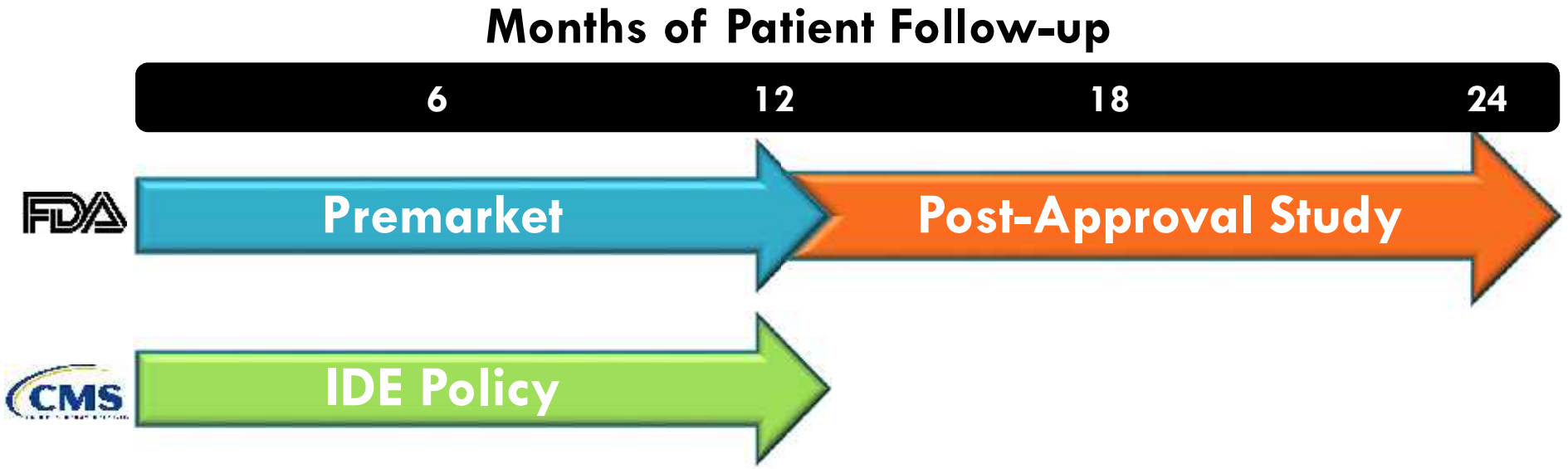
Adjudication in Conventional FDA Approval

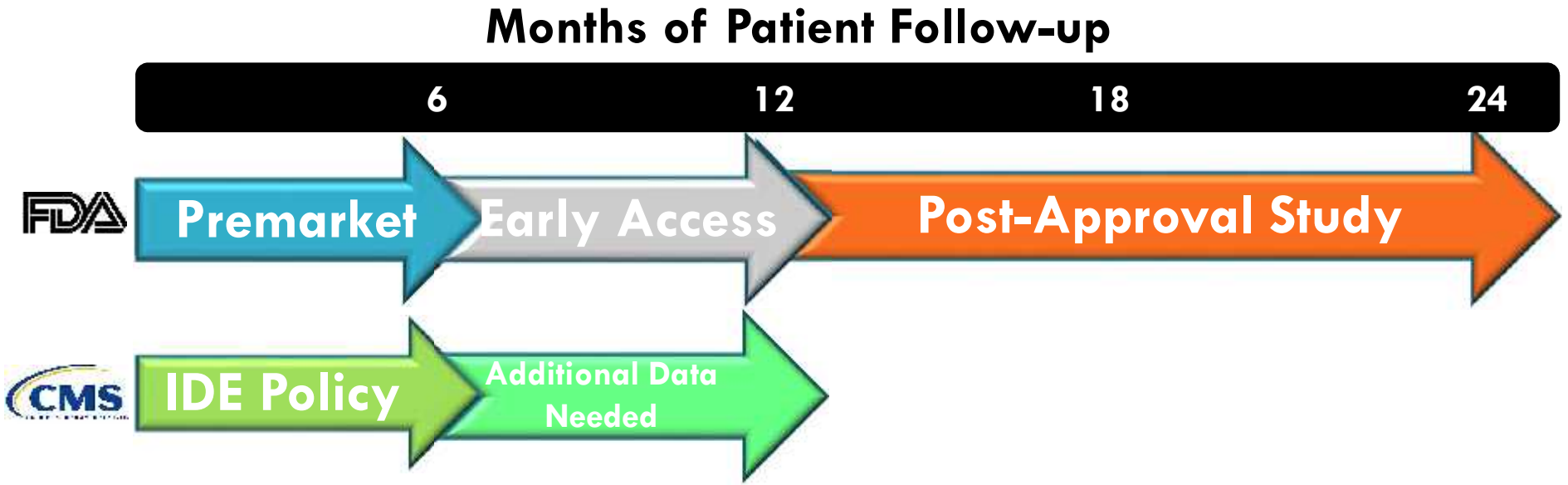


- Adjudication already specified when necessary for conventional FDA approval where CMS requires CED
  - Left Atrial Appendage (LAA) Closure Therapy
    - *Stroke, adjudicated by type*

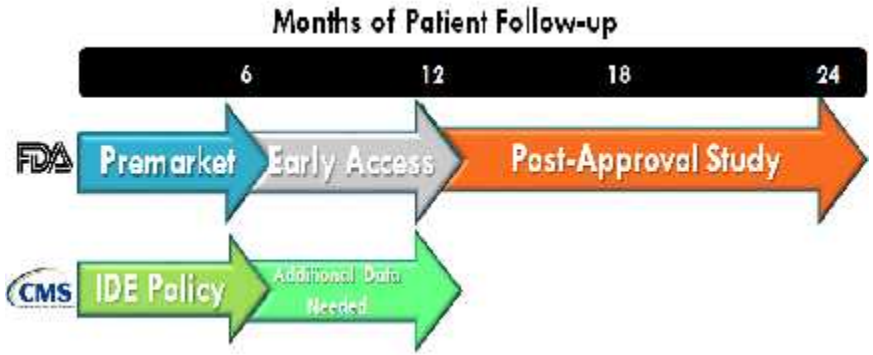
Two-phased Study



EAP Two-phased Study

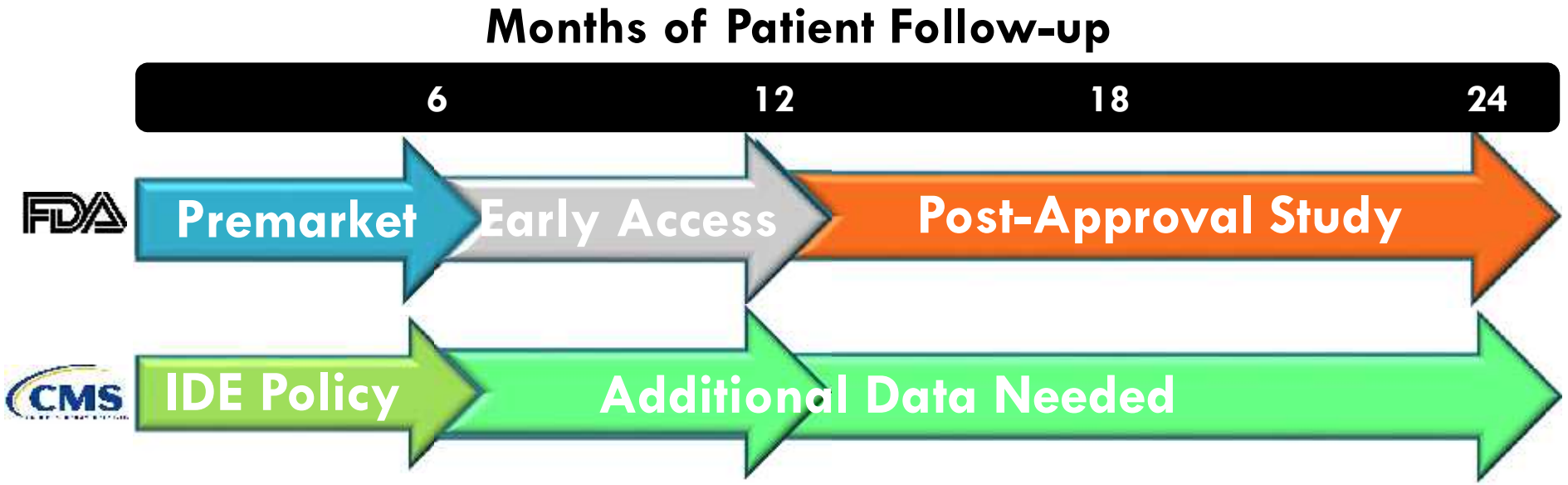


EAP Two-phased Study Adjudication



- Adjudication may play an increased role where further uncertainty is shifted to the postmarket setting
- Adjudication equivalent to conventional premarket follow-up duration important

Longer Term Data Collection Maybe Necessary



EAP Clinical Evidence That May Support Approval

1) Two-Phase Studies

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Considerations for Reducing CMS Postmarket Data Needs

- Inclusion and representativeness of CMS beneficiaries in premarket studies
- Collection of meaningful health outcomes through at least conventional study duration

EAP Clinical Evidence That May Support Approval

1) Two-Phase Studies

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Streamlined Clinical Trials But Meaningful Health Outcomes

Streamlined Clinical Trials But Meaningful Health Outcomes

Intermediate and Surrogate Endpoints

FDA may…

rely on assessments of a device's effect on an intermediate or surrogate endpoint that is reasonably likely to predict clinical benefit (on the condition that remaining uncertainty about the predictive relationship between a surrogate and clinical benefit is minimized through confirmatory post-approval studies or on the condition that clinical benefit is verified through confirmatory post-approval studies

Practical Considerations

- Involvement of all stakeholders in the premarket study design

- *Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population*

Thank you

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