



NINDS Perspective: Need for an Endovascular Platform

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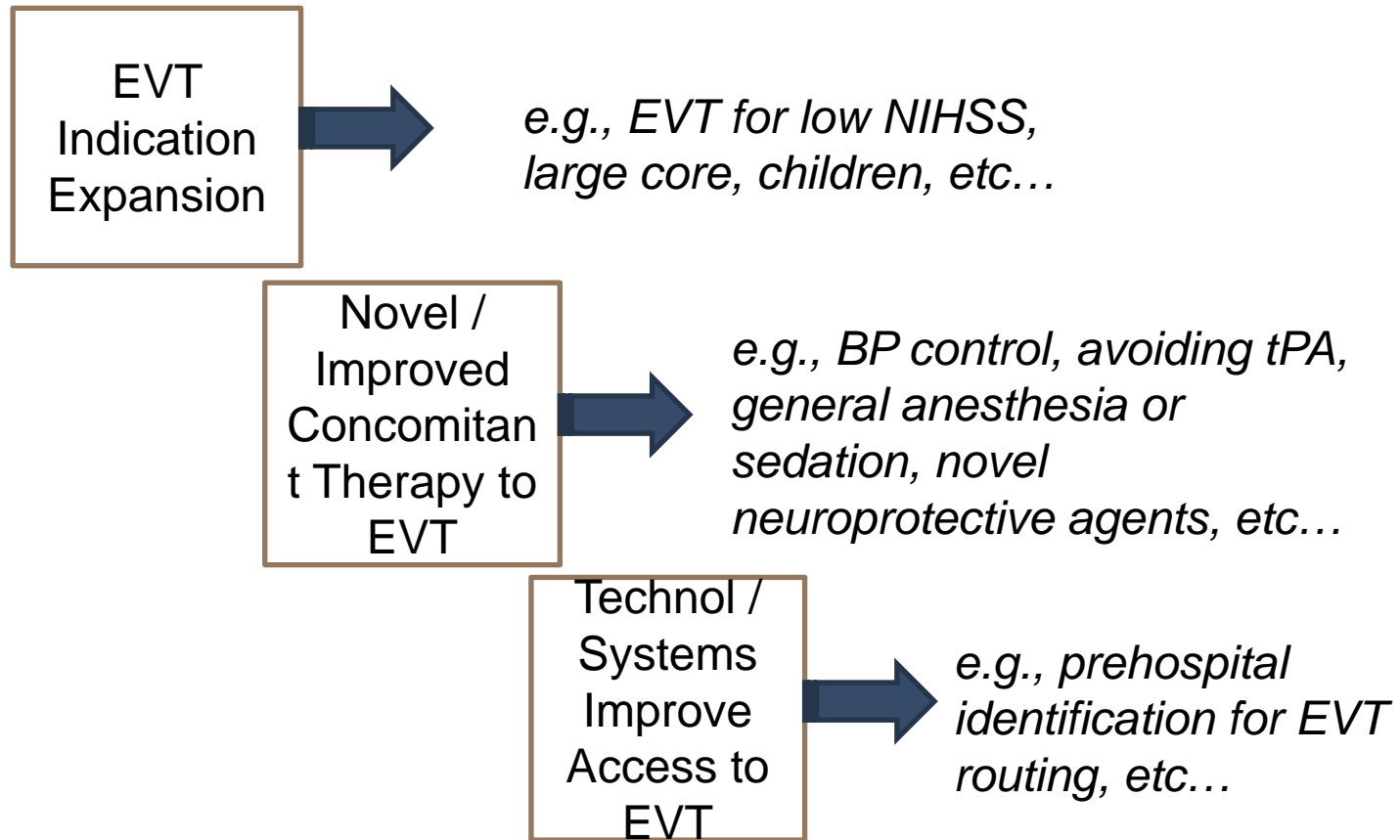


Disclosures

None relevant to this talk



How did we get here?



Deluge of EVT Proposals to NINDS



Guidance Snapshot



Master Protocols for Drug and Biological Product Development

Draft Guidance

What Is A Master Protocol?

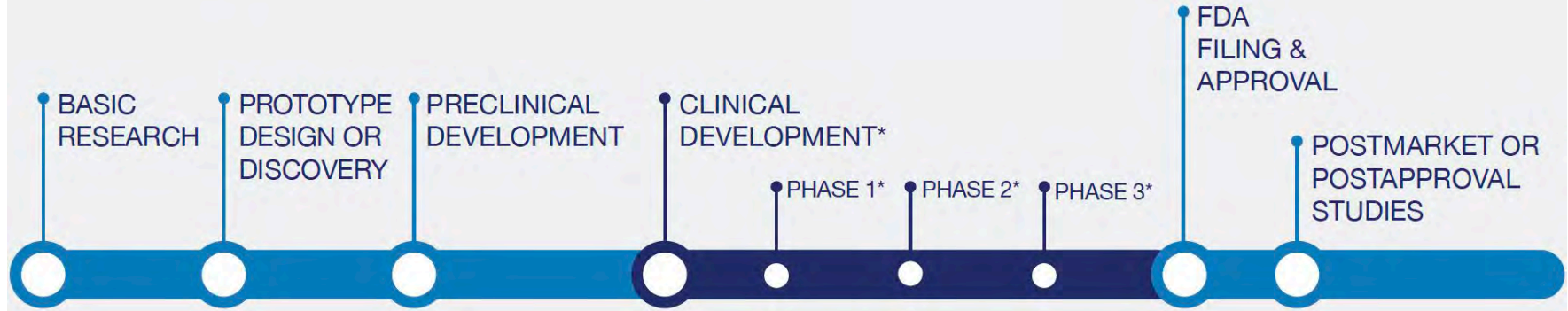
One designed with multiple sub-studies:

- May have different objectives
- Are coordinated within an overall study structure to evaluate one or more medical products
- One or more diseases or conditions



Drug Development Timeline

***When to Apply the Guidance Recommendations**



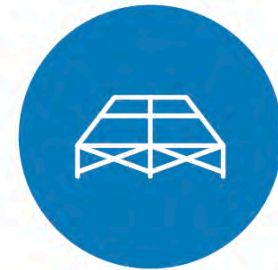
Umbrella trial

Evaluates multiple medical products at the same time for a single disease or condition



Basket trial

Evaluates a medical product for multiple diseases, conditions, or disease subtypes








Platform trial

Evaluates multiple medical products for a disease or condition and medical products can enter or leave the platform in an ongoing manner



Building off previous and growing experience, the NINDS pursued a clinical trial platform to answer the many questions we have been receiving in the EVT space

					
Platform	STAMPEDE	GBM AGILE	Healey ALS	EPPIC NET (HEAL)	ACTIV
Condition	Prostate CA	Glioblastoma	ALS	DPN	COVID-19
Year started	2005	2019	2020	2020	2020
Agents/pops tested	10	4	5	>4	27
Centers	>120	>23	>54	>24	>620
Patients	>10,000	>550	>1000	>1000	>20,000



NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY
Funded by a Grant from the National Institutes of Health



Coordinating Center

Renewal RCC

New RCC

Legacy RCC

Overview

- Launched in 2013
- 17 active studies
- 27 regional centers with over 500 satellite stroke hospitals, a coordinating center (Cinn), and a data coordinating center (MUSC)
- Phase 1/2 and phase 3 clinical trials (ancillary studies) and biomarker studies to advance acute stroke **treatment, prevention, and recovery**



Next up: **Design and Logistics Overview**

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