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Standardizing the Evaluation of Diagnostics

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C-Path

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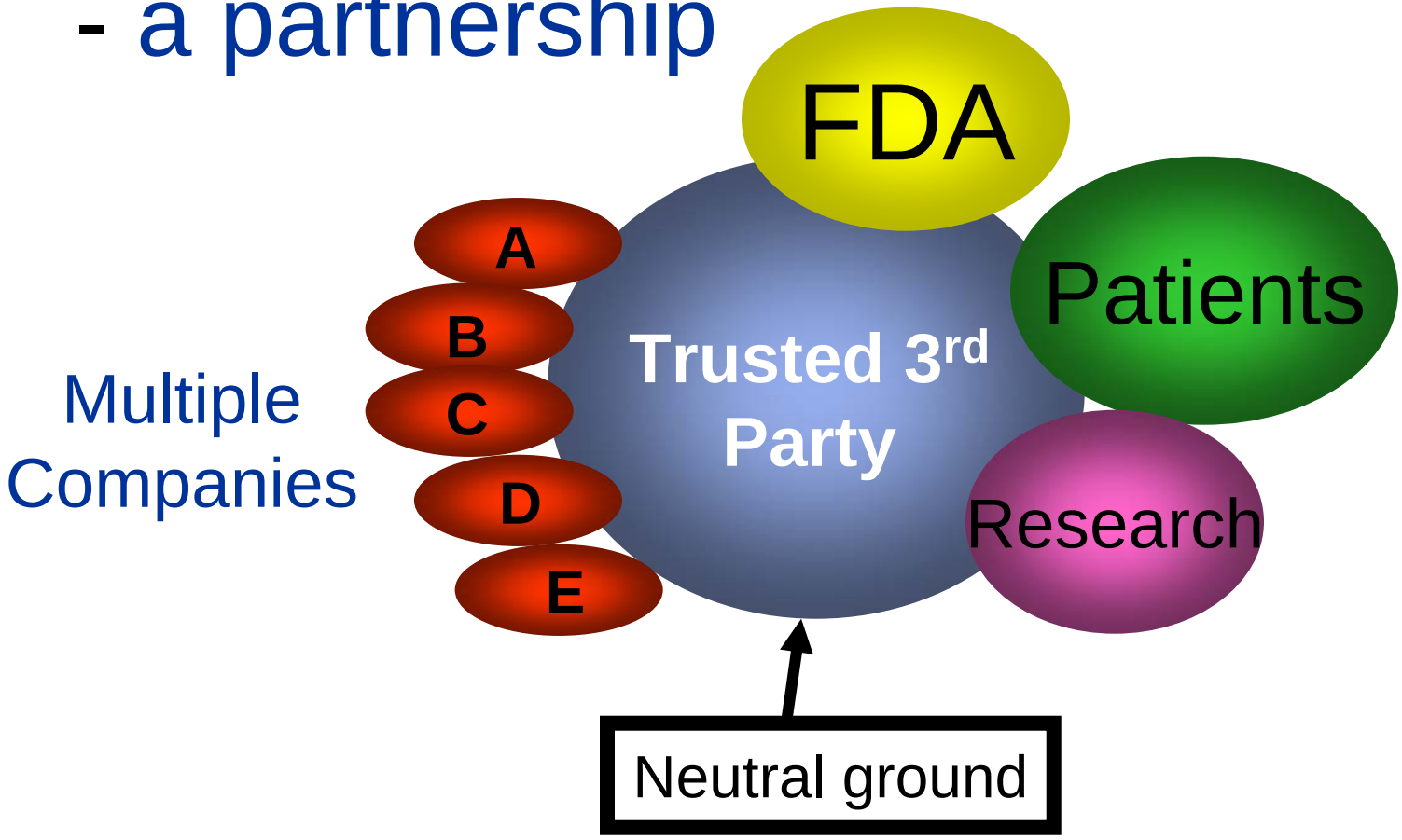
What is needed for Change?

- a partnership



C-Path Consortia

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Safety

Predictive Safety Test Consortium

Efficacy

Lung cancer - targeted therapy & companion diagnostics

Dosing

Warfarin - dosing based on genotype

Major Disease

Coalition Against Major Disease (CAMD)

Alzheimer's and Parkinson's diseases

How to improve

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Get it right at the start

- Best of class methods
- Proof of reliability and performance
- Standardized data submission process

An ‘Underwriter’s Lab’
for diagnostics

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United States Diagnostics Standards
(USDS)

- standardize clinical samples-analytes
- evaluate and certify laboratory diagnostic tests
- data available for submission to FDA

USDS

Why not standardize diagnostics?

Standards setting in other industries:

USP U.S. PHARMACOPEIA
Drugs

SEMATECH
Semiconductors

USDS Concept

- Non-profit
- Associated with C-Path
- Initial funding SFAz

FDA view

Steven Gutman, FDA
Director, Office of *In Vitro* Diagnostic Devices

"It is our belief that C-Path's EGFR project would … standardize the way studies of diagnostics for targeted therapy are performed in preparation for submissions for approval."

"The FDA and OIVD need projects like the ones C-Path is proposing to provide … a template for the validation of diagnostics (biomarkers) in guiding targeted cancer therapy."

"The future of personalized medicine rests on the ability of projects like this to be undertaken and for information and lessons learned to be broadly utilized and shared."

USDS Concept
Two Types of Analysis

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1) Analytical evaluation

performance characteristics are measured

2) Clinical evaluation

where clinical data is available.

- association with a clinical condition
- prediction of treatment response

USDS
meeting needs

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- Standard sample repository
- Neutral lab testing facility
- Test = predicate?
- Lab developed tests: evaluation

USDS oversight of ….
- process, protocol and reporting

USDS
Value Added

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- Improve reporting to FDA
- Compare competing products
- Evidence for payer/providers/investors

FAQs

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Is USDS another regulatory hurdle?

- No, it is not required. Additional steps are not added

How does USDS relate to NIST, CDC, CLSI, CAP,etc?

- Non-duplicating, working relationship to partner on standards and methods

What if I don’t like the result?

- Manufacturer can use data as it wishes

How is IP protected?

- Data is confidential. Comparisons are voluntary.

How will reference standards be maintained?

- To be determined on case by case basis