Why Samples are So Important in Precision Medicine Clinical Trials

BIOFORTIS
Precision Medicine ///Accelerate

In precision medicine trials, patient samples (biospecimens) are as important as patients themselves; critical decisions are dependent on sample analyses.

DRUG DEVELOPMENT IS INCREASINGLY DEPENDENT ON BIOMARKERS
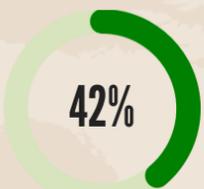
42% — 42% of all drugs in development are precision medicines

73% — 73% of oncology drugs in development vs. are precision medicines [1]

Probability of Success With and Without Selection Biomarkers [2]

Phase	Without Biomarkers	With Biomarkers
Phase I - II	63%	76%
Phase II - III	28%	46%
Phase III - NDA/BLA	55%	76%
NDA/BLA - Approval	83%	94%
Phase I - Approval	8%	26%
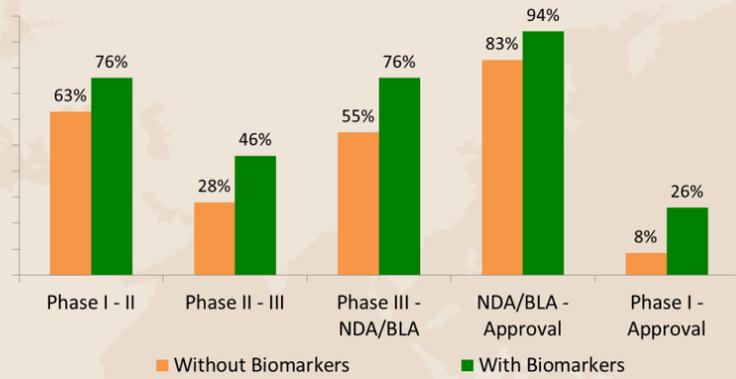
Studies using biomarkers for patient selection have a 17.5% greater chance of success (phase 1 to approval)

THE USE OF BIOMARKERS FOR PATIENT SEGMENTATION ENHANCES STUDY OUTCOMES
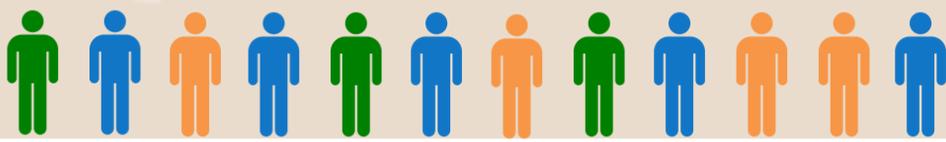
Biomarker analyses are based on patient samples.

Drug interactions are also measured using patient samples.
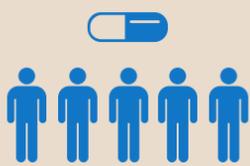
Biomarker A

Biomarker B

Biomarker C

A study examined the safety and efficacy of 346 phase I oncology trials with over 13,000 total patients. The meta-analysis included 58 treatment arms that employed precision medicine, and 293 that did not.

30.6%

4.9%

2.95 months

5.7 months
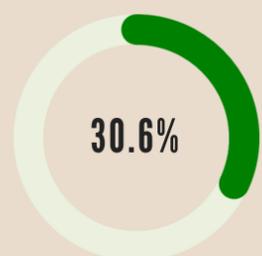
The oncology trials employing precision medicine showed the average tumor shrinkage rate was 30.6%, compared to 4.9% in the trials that did not.
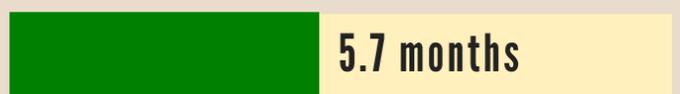
Patients in precision medicine arms also had a longer progression-free survival duration compared to other arms (median 5.7 months vs. 2.95 months).

LABMATRIX LETS YOU SEE WHAT'S GOING ON WITH YOUR PATIENT SAMPLES

60 - 70% [4]

60 - 70% of regulatory submission data in precision medicine trials is based on sample analysis results - which is why it is so important to know the "what, when, and where" aspects of biosamples in and across your studies.
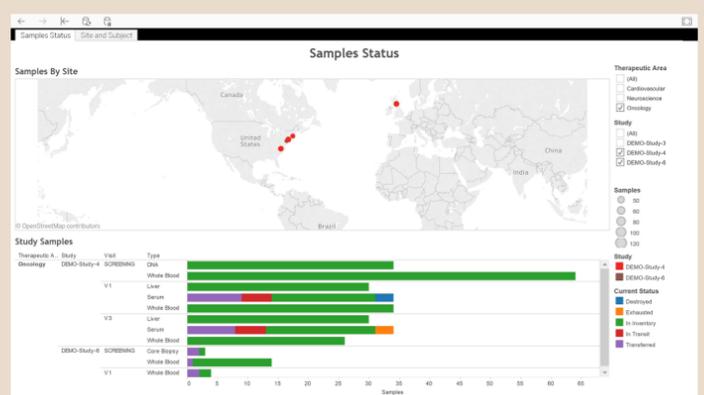
Our Labmatrix software solution lets you see up-to-date biosample activities and alerts with study, site, and other dynamic drill-down dashboards.

Labmatrix users can immediately access pre-configured biosample reports (e.g. collected vs. planned reconciliation) across your clinical trial partners with the click of a button.

REFERENCES

1. The Personalized Medicine Report - 2017: Opportunity, Challenges, and the Future. Retrieved April 5, 2017, from http://www.personalizedmedicinecoalition.org
2. (2016, May 18). Precision Medicine Yields Better Outcomes for Patients in Phase I Clinical Trials. Retrieved April 5, 2017, from https://www.asco.org
3. Clinical Development Success Rates 2006-2015 - BIO, Biomedtracker, Amplion 2016. Retrieved April 5, 2017, from https://www.bio.org
4. Engelhart, Mark. Inside the Central Laboratory Model For Clinical Trials Diagnostic Testing. Retrieved April 5, 2017, from http://www.pharmavoice.com/article/2016-06-diagnostic-testing/

More info: www.biofortis.com