

PP04

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Pre-screening Process Flow



ABSTRACT

Screening patients for biomarker-selected clinical trials requires a substantial amount of time, with a low chance of enrollment. Patients with a diverse set of biomarkers should be matched with therapies from which they are most likely to benefit. Allowing for optimal patient identification leads to faster enrollment in core protocols, decreases the downstream impact to sites, increases site commitment and saves time and money. Subjects who are confirmed biomarker positive in the pre-screening study may be enrolled in the Phase 2 or 3 interventional trials. Patients who fail to screen in one interventional trial might be eligible for another interventional trial within the same program. For these patients, molecular eligibility data needs to be transferred to the target study. This poster describes the overall process of data transfer between pre-screening and interventional studies and data transfer between the interventional studies.

BACKGROUND

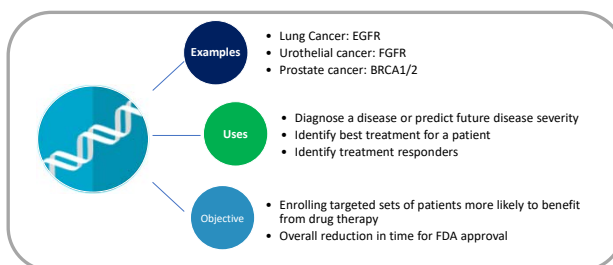
What's happening in the Industry¹

- 55% of all oncology trials in 2018 involved the use of biomarkers, as compared with 15% in 2000
- Biomarkers such as PD-1/PD-L1/2, ALK, TIL, CD4, MRD, and BRAF have shown the fastest growth
- Biomarker-driven personalized medicine approaches will lead to better patient outcomes by enabling early detection, identifying treatment responders and monitoring treatment, response and targeted therapeutic effect



What is a biomarker?

Biomarkers are molecules or measurements that indicate normal or abnormal process in your body and may be a sign of an underlying condition or disease. Various types of molecules, such as DNA (genes), proteins or hormones, can serve as biomarkers, since they all indicate something about your health. Biomarkers related to cancer may be produced by the cancer tissue itself or by other cells in the body in response to cancer. They can be found in the blood, stool, urine, tumor tissue, or other tissues or bodily fluids. Notably, biomarkers are not limited to cancer. There are also biomarkers for heart disease, multiple sclerosis, and many other diseases.



Next Generation Sequencing

Next Generation Sequencing (NGS) refers to advanced technologies that allow sequencing of DNA or RNA. NGS enables the interrogation of hundreds to thousands of genes at one time in multiple samples, as well as discovery and analysis of different types of genomic features in a single sequencing run.



- RNA & DNA based assays
- Extracted from: blood, saliva, tissue, urine



- NGS is used to identify clinically relevant alterations
- Can detect the four main classes of genomic alterations – base substitutions, insertions or deletions, copy number alterations and gene rearrangements



- PF: Results of genetic variation tests
- BS: Details regarding the biospecimens and extracted samples such as volume, specimen condition, DNA concentration, quality

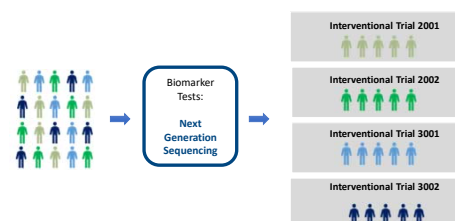
PRE-SCREENING PROTOCOL



A protocol with the focus to streamline patient identification using targeted biomarker inclusion criteria

PRE-SCREENING STUDY

Identify biomarker positive patients for interventional studies:

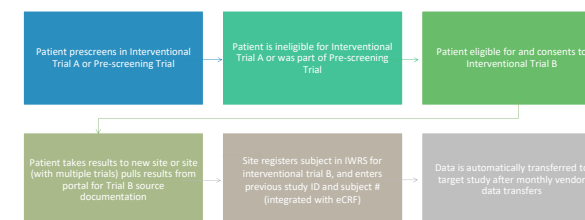


INTERVENTIONAL STUDIES

A patient who is ineligible for one interventional study, might be eligible for another interventional study within the same program.

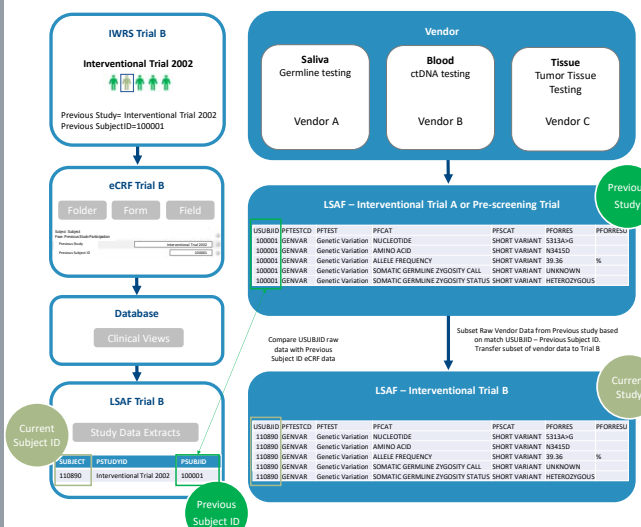


PROCESS FLOW



DATA FLOW

Patients might prescreen in one study and enter fully study screening in another trial within the same program. For these patients, molecular eligibility data needs to be copied over from one trial to another. Example below: Screen Failure subject from Interventional Trial 2002 transfers to Interventional Trial 2001



CONCLUSION

Biomarker data is automatically transferred from pre-screening study to target interventional study or across interventional studies. Transferring the subject's external biomarker data makes re-testing unnecessary, alleviating the burden on patient and site and are leading to cost efficiencies.

References
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