



**Global Harmonization Working Party**

GHWP Towards Medical Device Harmonization

# Industry Showcase: Sequencing and Mass Spectrometry

Bradford Spring

Global Head of Regulatory Policy and Intelligence

Roche Diagnostics



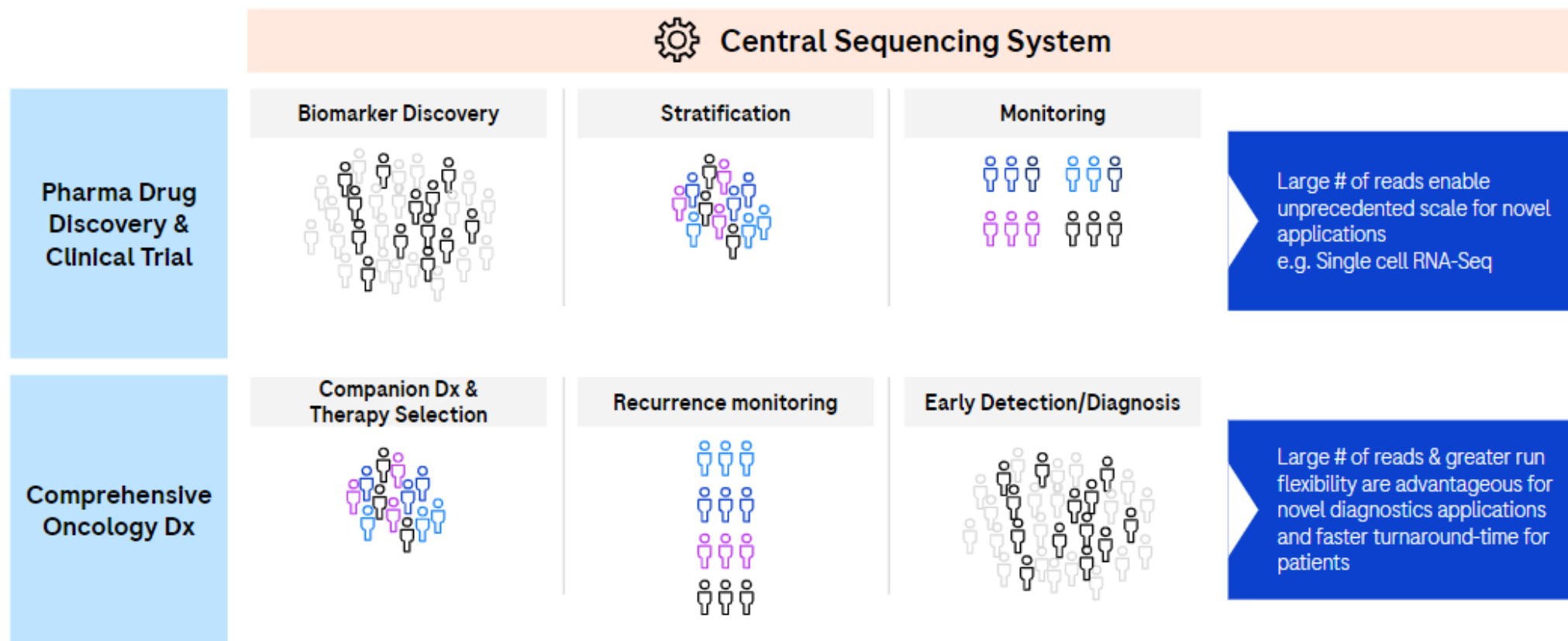
## Sequencing technologies and their role in diagnostics

- Sequencing technologies allow for the rapid sequencing of a large segments of DNA and even an entire genome
- Next generation sequencing (NGS) and newer, fourth generation technologies promise to accelerate “personalized” or “precision” medicine; tailoring treatments at the individual level
- Recent sequencing advancements also provide higher throughput at a lower cost with minimal sample preparation as compared to NGS



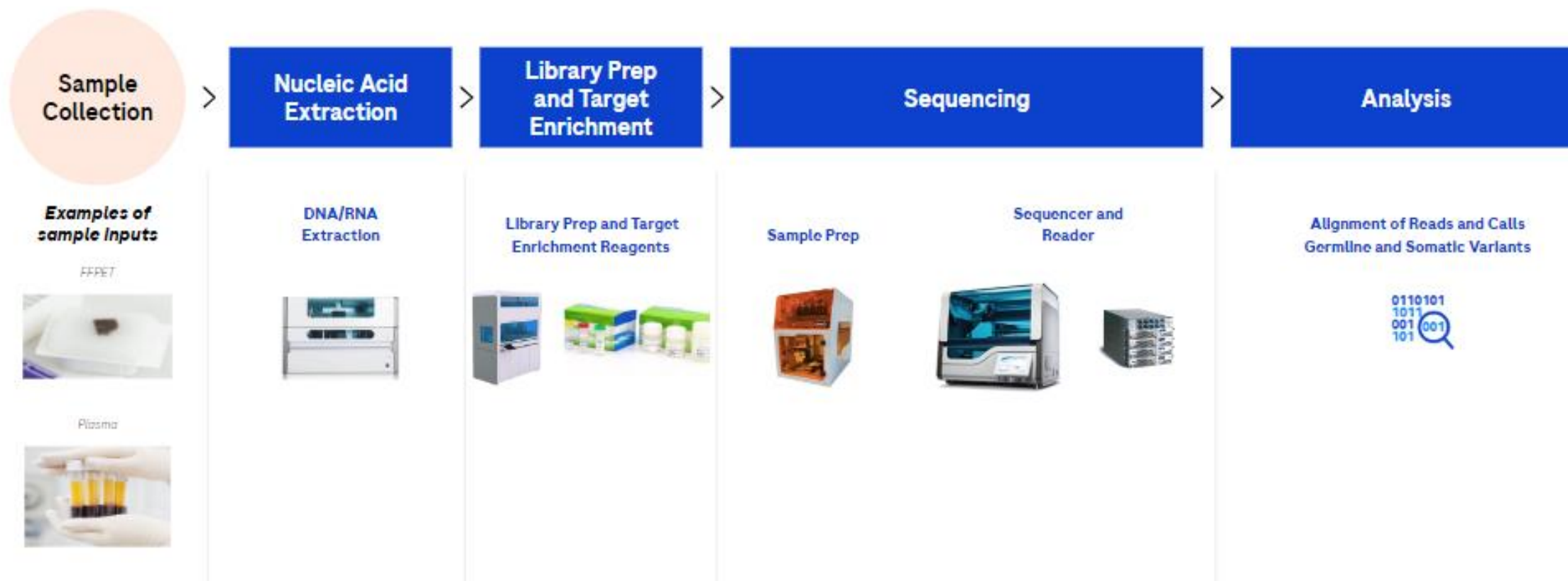
# Sequencing: Discovery and Clinical Applications

*Greater flexibility, scalability and faster time-to-result for patients*





# Complete Sequencing Workflow





# Automated Mass Spectrometry in the Clinical Lab

- Mass spectrometry is well known for its high sensitivity, specificity and accuracy and is used in several clinical indications including:
  - Immunosuppressant drug testing
  - Therapeutic drug monitoring
  - Drugs of abuse testing
  - Steroid measurements
  - Metabolic screening
  - Microbial identification
- However, the operational complexity, manual burden, lack of integration and standardization has kept this well characterized technology from many clinical laboratories.



# Mass Spec: Simplify and Automate

*Automated solutions addressing complexity with integration to lab informatics*



## Fully automated solution



Reduce human-induced errors



Reduced hands-on time



Shorter turnaround times



## Challenges and Opportunities for both technologies

- What is an appropriate comparator method to demonstrate accuracy?
- Is there an opportunity to leverage “real world evidence” and “in silico analysis” to reduce the burden of prospective clinical studies?
- Can a “predetermined change control plan” approach be used to release the vast array of new assays on NGS and Mass Spec platforms?
- The availability of well characterized, globally recognized standards will help simplify the validation of new or modified tests.

# Thank You