



Be the partner  
of choice for  
clinical trials



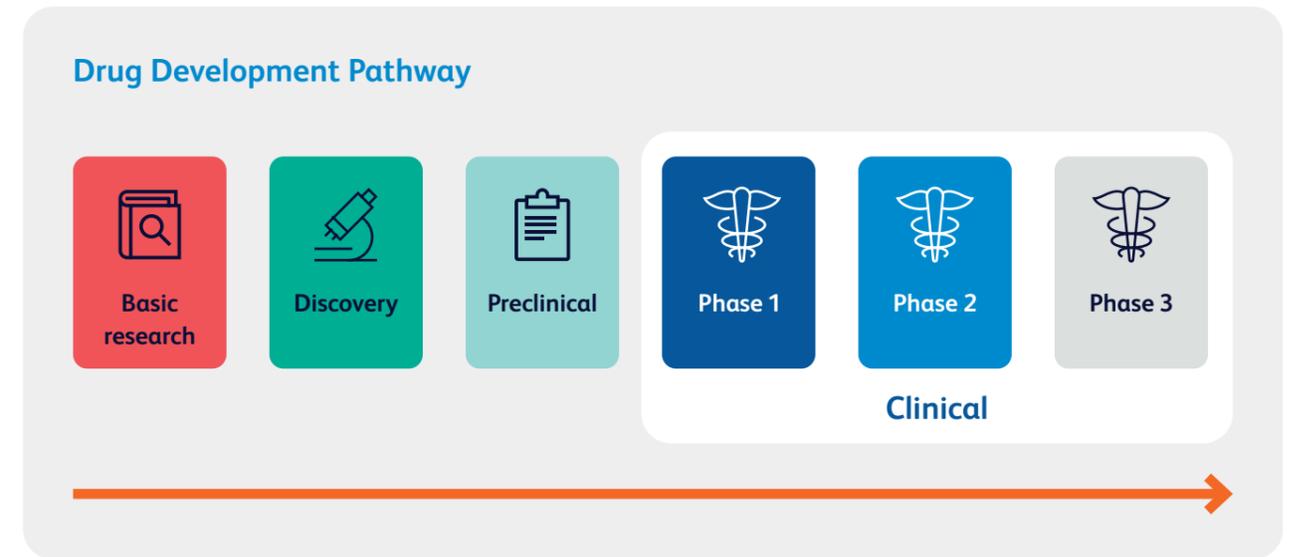
# Leverage the power of Next Generation Flow™ for a fully integrated, innovative clinical trials solution



## Next Generation Flow represents the latest step in the technological evolution of flow cytometry techniques

Flow cytometry has been widely used for decades as a highly sensitive tool for immunophenotypic analysis, and is playing an increasing role in biomarker detection in clinical trials, e.g. in CAR-T clinical trials.<sup>1</sup>

Next Generation Flow™ represents one of the latest advancements in this powerful technology, enhancing precision, efficiency, and standardisation to deliver peerless reproducible results.



## Surpassing the sensitivity, efficiency, and flexibility of other leading technologies, Next Generation Flow™ offers<sup>2,3</sup>:

Higher sensitivity than conventional 8-colour flow techniques

High concordance to polymerase chain reaction (PCR)-based and next generation sequencing (NGS) techniques

Faster turnaround of results (within the same day) than PCR-based and NGS techniques

Fundamental to clinical trial assessment of disease status is measurable residual disease (MRD): the small number of malignant cells that remain in the patient during or after cancer treatment. MRD plays an important role as a powerful and highly versatile biomarker.<sup>4</sup>MRD can be used as a biomarker for:



**Prognosis** – to predict the likelihood of a clinical event independent of treatment



**Response prediction** – to predict the likelihood of response to a particular treatment



**Monitoring** – to detect changes in the degree or extent of disease



**Efficacy** – to measure the response to drug exposure

The EuroFlow™ consortium developed and evaluated Next Generation Flow methodology for the assessment of MRD in multiple myeloma (MM) and B-cell precursor acute lymphoblastic leukaemia (BCP-ALL), finding:

- High sensitivity of  $\leq 10^5$  comparable to RQ-PCR-based MRD detection<sup>2,3</sup>

- Significantly higher concordance between Next Generation Flow and PCR-based techniques compared with NGS
- Concordance rate of 98% when higher cell numbers are acquired.<sup>2,3</sup>



### Partner with BD to leverage this innovative technology through our complete clinical trials package

To support the large and expanding clinical trials landscape around BCP-ALL and MM, we provide antibody panels that follow the EuroFlow™ methodology, offering precision MRD assessment and analysis in one integrated solution. CAR-T cell therapy is currently a major player in the BCP-ALL and MM cell therapy pipeline, and Next Generation Flow™ solutions offer vital assessment and profiling throughout the CAR T-cell clinical trials lifecycle.<sup>5,6</sup>



#### Multiple myeloma

Improve the precision and reliability of MRD and complete response assessment with the MM-MRD antibody panel:

- High sensitivity, close to 10<sup>6</sup>
- Methodology is endorsed by the International Myeloma Working Group<sup>37</sup>



#### CD38 multi-epitope

Identify the CD38 molecule on plasma cells, even in patients under anti-CD38 therapy with the CD38 multi-epitope reagent:

- The CD38 multi-epitope is included in the MM-MRD antibody panel<sup>9</sup>



#### B-cell precursor acute lymphoblastic leukaemia

Assess treatment efficacy and enhance therapeutic decisions with the BCP-ALL MRD antibody panel:

- Highly sensitive, close to 10<sup>5</sup>
- Discriminates between normal and malignant BCPs in 99% of studied BCP-ALL patients
- Applicable in >98% of samples as specific primers and probes are not needed<sup>7</sup>



#### MRD evaluation data analysis

Improve data quality and analysis efficiency with the complete automated and standardised BD Infinicyt™ software:

- CE-marked in vitro diagnostic (CE-IVD) solution using validated EuroFlow™ reference databases and offering 21 CFR part 11 features

### Overcome workflow challenges with complementary technologies from BD

To support this cutting-edge technique, we offer a suite of integrated solutions to enhance your offering and optimise your workflow.

#### Enhance standardisation and collaboration across sites with the BD FACSLyric™ Flow Cytometer

Our large global install base, in industry and academia, of the IVDR-compliant BD FACSLyric™ Flow Cytometer supports standardisation of workflows, reproducibility of results and scalability, providing flexible automation to support your clinical trial set up.

BD FACSuite™ Application enables acquisition and analysis for BD CE-IVD assays with predefined assay templates but also for user-defined assays and enables seamless assay portability, facilitating collaboration and reproducibility between instruments and sites.

It also supports 21 CFR Part 11 features, like electronic record integrity through password protection, audit trail, electronic signatures, and installation qualification and operational qualification procedures.

#### Streamline your workflow with the BD FACSDuet™ Sample Preparation System\*

Integrating seamlessly with the BD FACSLyric™ Flow Cytometer, the BD FACSDuet™ Sample Preparation System drives efficiency, consistency, and traceability through automation of sample preparation and antibody cocktailing.

Further efficiencies can be achieved using the BD FACSDuet™ Premium Sample Preparation System with on-board washing and centrifugation: a wide variety of assays are accommodated, hands-on time is reduced and resources are maximised for both Lyse-No-Wash and Lyse-Wash-assays.

#### Unlock the potential of flow cytometry-based CDx solutions

BD has an experienced team and leading flow cytometry technologies to support comprehensive CDx co-development from discovery to global commercialization. We offer the flexibility to collaborate at any stage of therapeutic, biomarker or diagnostic development.

### Partnering with BD gives you access to a complete Next Generation Flow™ package to support you at every stage of your clinical trial

We can support you to deliver:

- Innovative, scientifically validated clinical trials solutions with Next Generation Flow™
- Rapid MRD evaluation turnaround times coupled with increased automation for efficient analysis, reduced hands-on time, and minimised potential for error
- Fully validated solutions that comply with CE-IVD regulatory requirements<sup>8</sup>, respectively, to provide dependable outputs
- A standardised, fully integrated approach enhancing data quality and supporting consistent collaboration and scalability across sites from sample preparation to data analysis

#### Discover more about the ways BD can enhance your clinical trial

Let's discuss how working with BD could support you to differentiate your offering and be the clinical trials partner of choice. Visit our website or get in touch to learn more about our integrated package and find out how you could get the best out of your clinical trials with Next Generation Flow™.

## References

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BD Flow Cytometers, BD FACSDuet™ Sample Preparation System and BD FACSDuet™ Premium Sample Preparation System are Class 1 Laser Products.



BD FACSDuet™ Sample Preparation System, BD FACSDuet™ Premium Sample Preparation System, BD FACSLytic™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ Application, BCP-ALL MRD Panel, MM MRD Panel, CD38-multi-epitope-FITC and BD Infinicyt™ analysis software are in vitro diagnostic medical devices bearing a CE mark.

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