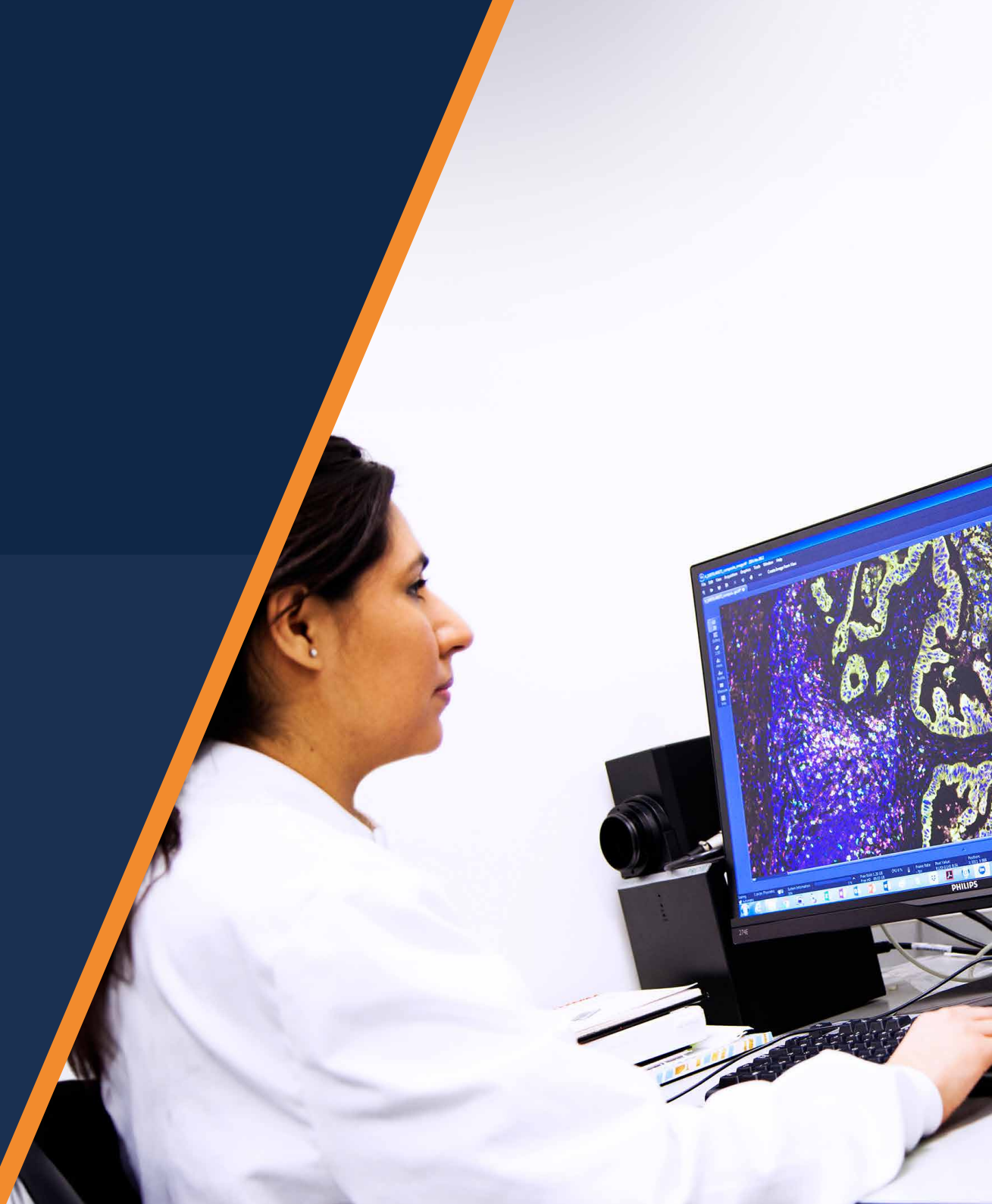
CONCEPT LIFE SCIENCES

Biomarkers

Drug Discovery & Development from Concept through to Clinic

November 2023



Our Custom Biomarkers Services

We can help you determine the optimal method for detecting and measuring biological responses to an intervention or within a disease setting, at any stage of the drug development pipeline.

Our tailored solutions and bespoke method optimisation ensures the most reliable and efficient approach is utilised in your scientific program.

We have extensive experience in a comprehensive range of biomarker identification technologies and services:

- Histology, spatial biology and image analysis
- Molecular biology
- Cellular analysis
- Secretome analysis
- Biophysical characterisation
- Bioanalysis

Let's talk about your unique Drug Discovery & Development journey

conceptlifesciences.com

Concept Life Sciences

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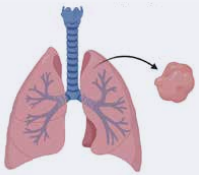
Service & Technology Overview



Tissue Biopsy

PBMC & Biofluids: Serum, Plasma etc

In vitro cell culture

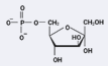
Biomarker types

Cell

Protein

Protein Modification

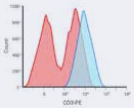
Nucleic Acids



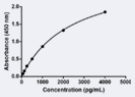
Metabolite

Technologies

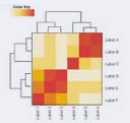
Histology & Image Analysis



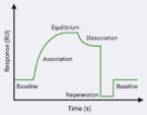
Flow Cytometry



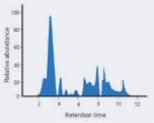
ELISA, MSD, Luminex



qPCR, Bulk & Single Cell RNA seq



SPR and CGI



Bioanalysis

Molecular Biology

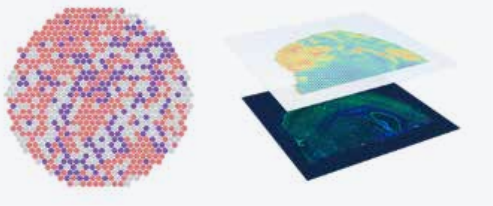
Discovery to Target Validation: Providing insight into mechanisms of action and biological pathways

Omics based approaches provide a robust and ultrasensitive method for biomarker discovery and justification of targets for therapy

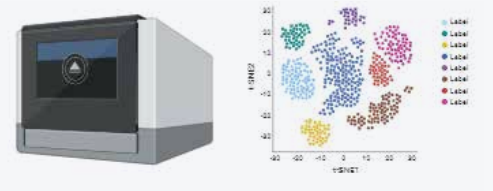
- Identification of candidates
- Molecular signatures of disease
- Single-cell or tissue-specific transcript patterns
- High precision methodology

At Concept Life Sciences we offer:

- Isolation of single cell suspensions for single cell RNA-Seq
- Generation of high quality library preparations
- Use of Qubit™ & Agilent® instrumentation for library quantity and quality assessment



- 10X Genomics Visium™ Platform
- NanoString GeoMx® Platform
- Fresh Frozen or FFPE Tissue



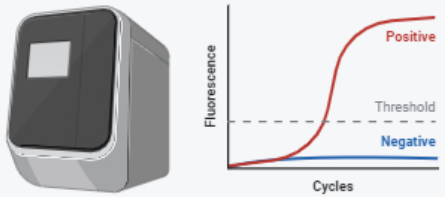
- 10X Genomics Chromium Controller™
- Gene Expression, V(D)J & CITE-Seq

Target validation is an important step in biomarker development. Molecular biology techniques can identify:

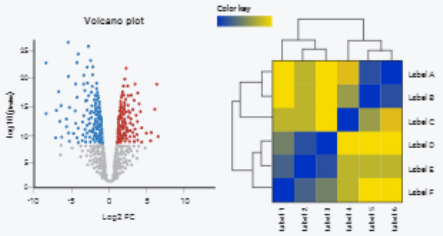
- Gene mutations
- Circulating tumour DNA (ctDNA)
- Gene overexpression
- Pathway analysis

At Concept Life Sciences we can isolate RNA/DNA from a broad range of sample types to meet your needs, including:

- Cultured cells
- PBMCs
- Fresh or frozen tissue
- Fixed-formalin paraffin embedded (FFPE) tissue



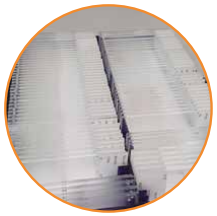
- Primer Design & Efficiency Testing
- Tissue Specific Validated Housekeeper Genes



- Bulk RNA-Seq
- ATAC-Seq

Histology & Image Analysis

Following the guidelines set out by GCP we offer an end-to-end service enabling visualisation and quantitation of protein and RNA biomarkers within a tissue context



Source

Tissue Sourcing

- Recommend and source control or diseased tissue

Process

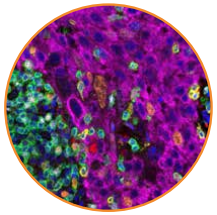
Processing, Embedding & Sectioning Services

- Formalin-fixed paraffin-embedded processing
- Fixed-frozen & fresh-frozen processing

Stain

Fully Automated Staining

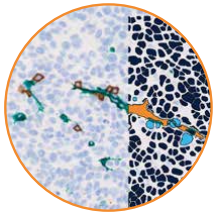
- An Akoya Biosciences Qualified CRO service provider
- Provide a database of suitable pre-optimised antibodies for biomarkers



Image

High-Performance Slide Scanning

- Whole Slide Imaging
- Spectral Unmixing



Analyse

VISIOPHARM®

State-of-the-art Digital Pathology Quantification

- Artificial Intelligence (AI) & Deep Learning
- Assist with data interpretation throughout the study and provide guidance on next steps

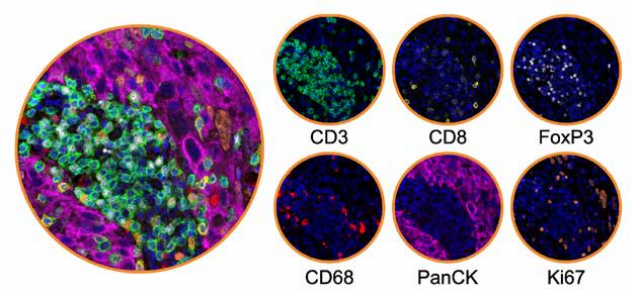
Immunohistochemistry Assays

Visualise and quantify cellular responses to drug treatment through detection of multiple biomarkers on the same tissue section using one of our automated multiplex immunofluorescence staining assays

Opal Classic

Bespoke assays relying on primary / secondary antibody binding

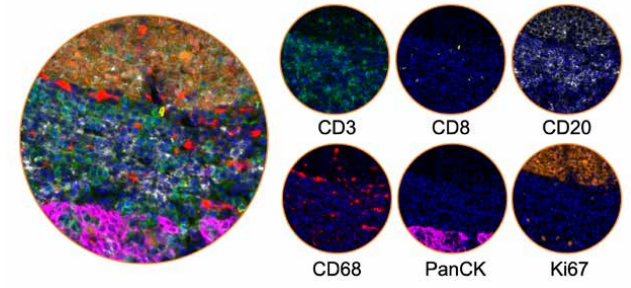
- Up to 8 biomarkers + nuclear counterstain
- Flexibility to select novel & custom biomarkers
- Can be developed for multiple species



PhenoCode™ Signature Panels

Pre-optimised assays utilising barcode-based technology

- Up to 6 biomarkers + nuclear counterstain
- Panels designed to address key questions in immuno-oncology
- Optimised for human tissue
- Reduced panel optimisation times



Spatial *In Situ* Hybridization

Spatial mapping and confirmation of gene signatures

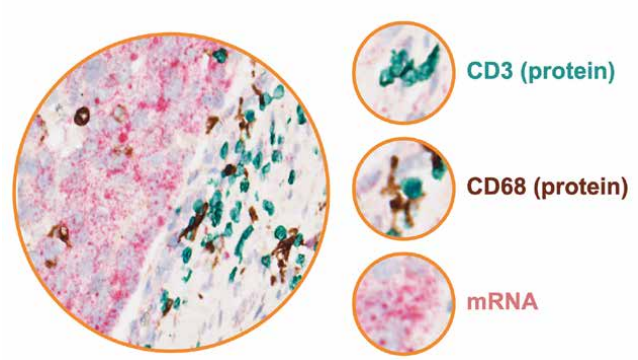
Amplify target-specific signals at single cell resolution, in highly sensitive and specific molecular diagnostic assays

- RNAScope™ and BaseScope™
- Fully automated
- High precision methodology
- Dual ISH and IHC
- Tissue or cell pellets

RNA and Protein Multiplex

Simultaneous detection of both RNA and protein on the same tissue section

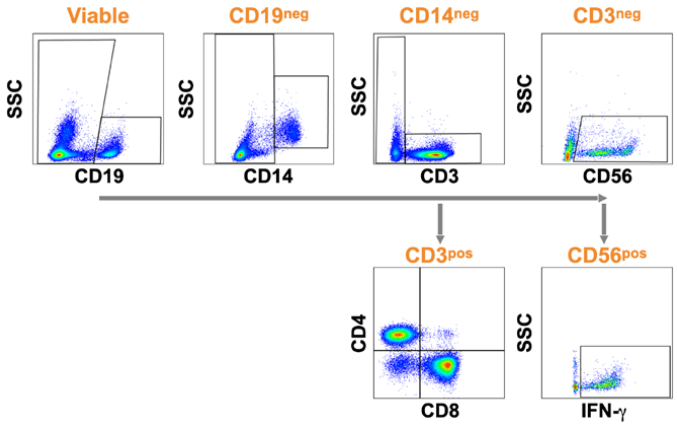
- Up to 4 RNA targets in combination with 2 proteins + nuclear counterstain
- Quantifiable through our in-house image analysis platform



Cellular Analysis: Flow Cytometry

Our flow cytometry services offer the ability to assess:

- Concurrent identification of cellular phenotypes
- Extracellular, intracellular and intranuclear markers
- Cell signalling and phosphorylated protein detection to study signalling pathways
- Cell cycle analyses - a powerful tool to assess cell proliferation and activation
- Mechanism of action (MOA) and assessment of immunomodulation
- Determine the binding of a large molecule to a cell surface target
- Assess efficacy and pharmacodynamic (PK/PD) endpoints in drug development

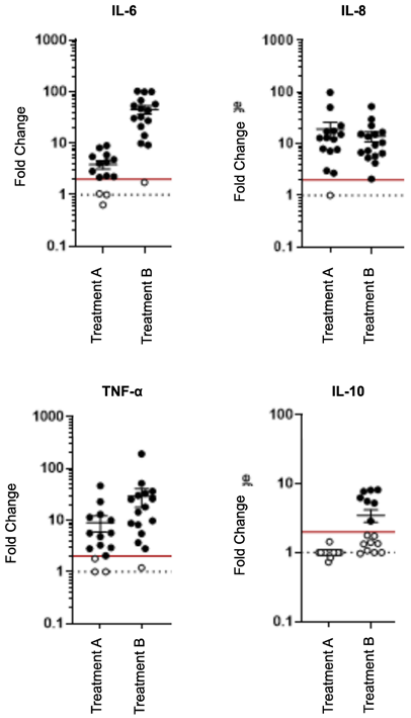


Secretome Analysis: Multiplex Immunoassays

Using multi-analyte detection to accurately identify reliable biomarkers and measure therapeutic responses

From early stage-predictive toxicology, mechanism of action or assessment of therapeutic effect, our robust Multiplex Immunoassays offer:

- Up to 65 analyte multiplex
- Preconfigured optimised panels
- Tailored customisable panels
- Highly sensitive detection levels
- Low sample volume
- Biofluids or *in vitro* samples



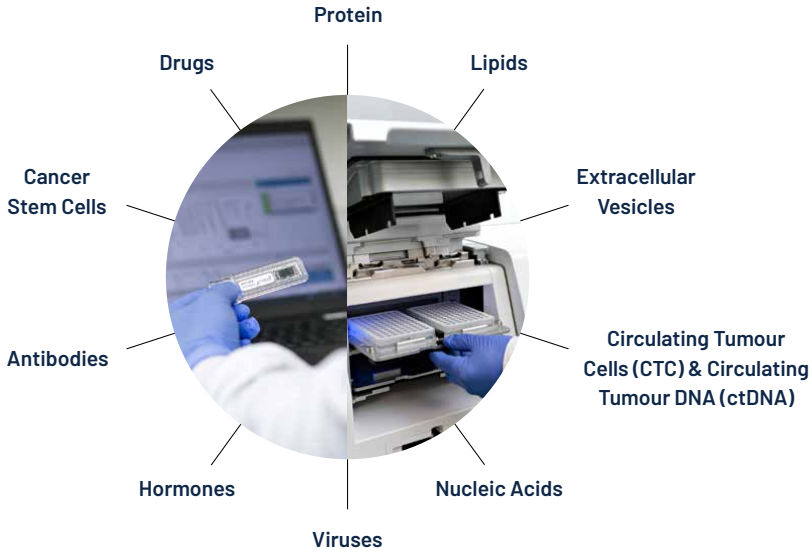
Biophysical Characterisation for Biomarker Analysis

High-sensitivity biomarker detection

Biophysical techniques allow the detection of biomarkers in clinical samples for early diagnosis and patient stratification

Grating-Coupled Interferometry (GCI) and Surface Plasmon Resonance (SPR) provide several advantages over conventional detection methods, including:

- Label-free
- High-throughput
- Non-destructive examination
- Simple miniaturisation
- Superior selectivity
- High reproducibility
- High sensitivity
- Calibration-free concentration analysis (CFCA)



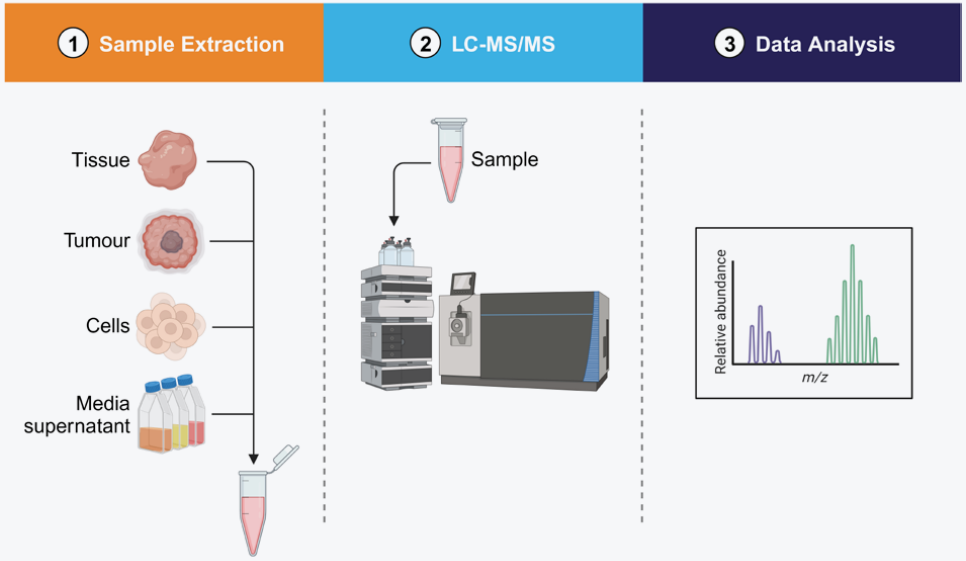
Bioanalysis for Biomarkers

Validated quantitative biomarker analysis

Bioanalytical techniques allow for quantitative analysis of biomarkers

With high levels of sensitivity and specificity, bioanalytical technology:

- Targeted quantitation of biomarkers in multiple matrices (including patient-derived samples such as serum, plasma, urine and tissues, as well as cells and culture medium)
- Low limits of detection facilitates the differentiation between healthy and diseased populations and detects small but significant changes in biomarkers in response to treatments, therapy or other interventions
- Full bioanalytical method validation allows biomarker analyses to be used as end points for clinical evaluations

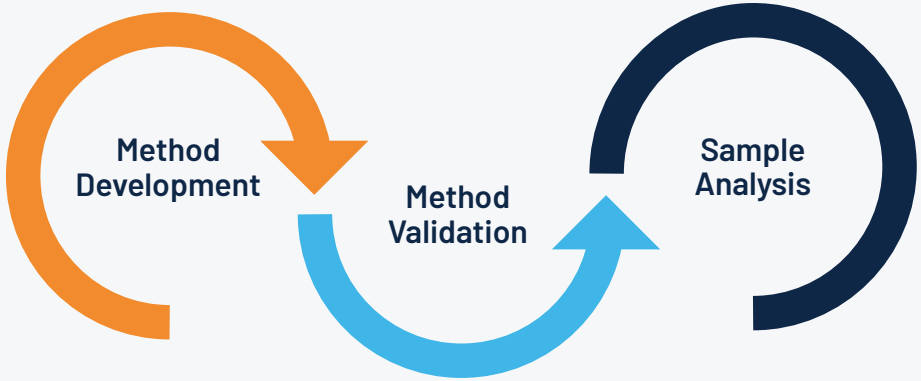


Liquid chromatography tandem mass spectrometry (LC-MS/MS) offers several advantages over other quantitative detection methods for biomarkers, including:

- Superior selectivity
- Highly sensitive
- Low detection level
- Quantitative
- Isotopically internal standards

At Concept Life Sciences we can assist you with biomarker detection through:

- Bespoke bioanalytical method development
- Specific instrument parameter optimisation for the compound of interest
- Bioanalytical method validation
- Sample analysis using validated bioanalytical method
- Fit-for-purpose (for exploratory research) through to fully regulatory compliant (for clinical analysis)



Drug Discovery & Development from Concept through to Clinic

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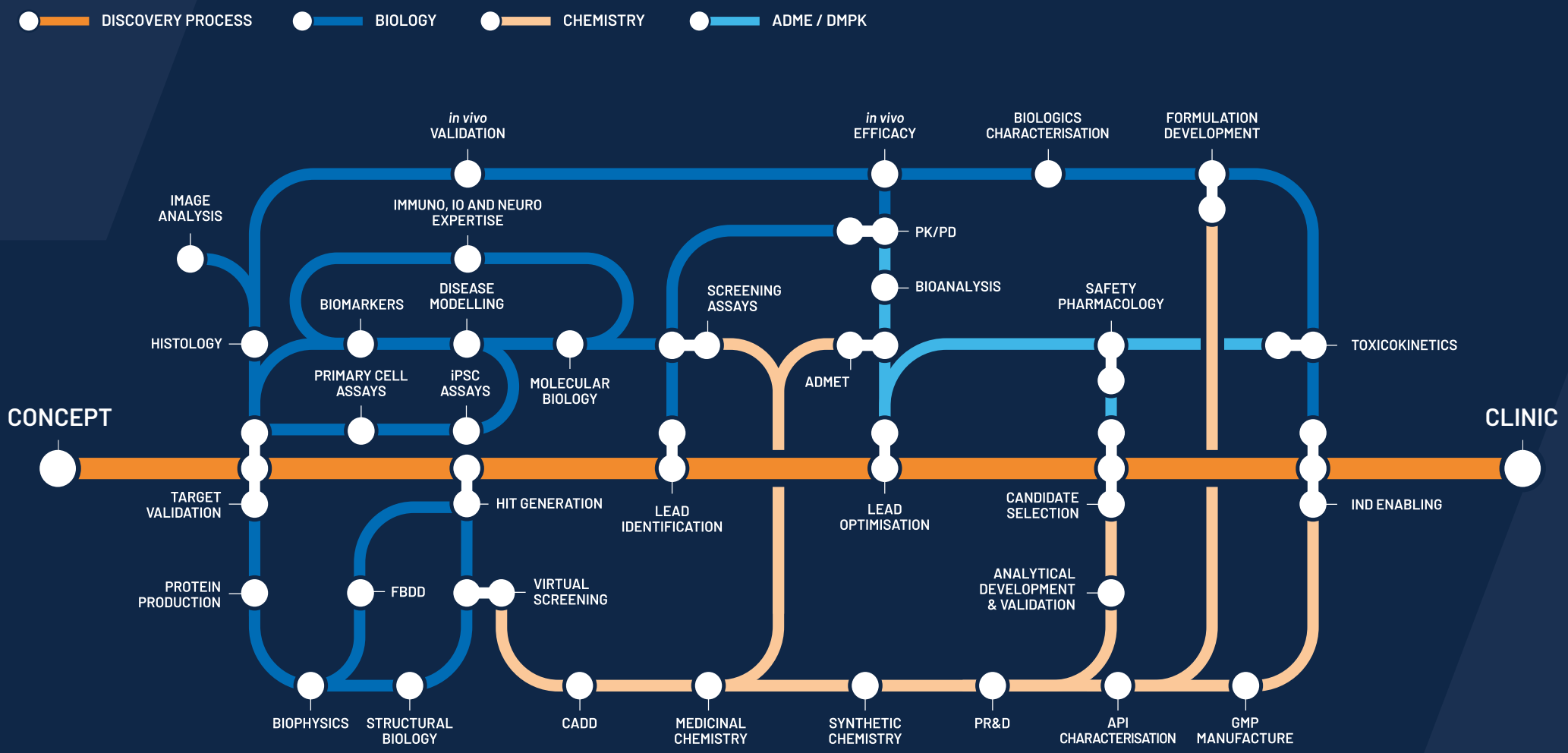

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