

# Overview of Svar Product Portfolio & Competition



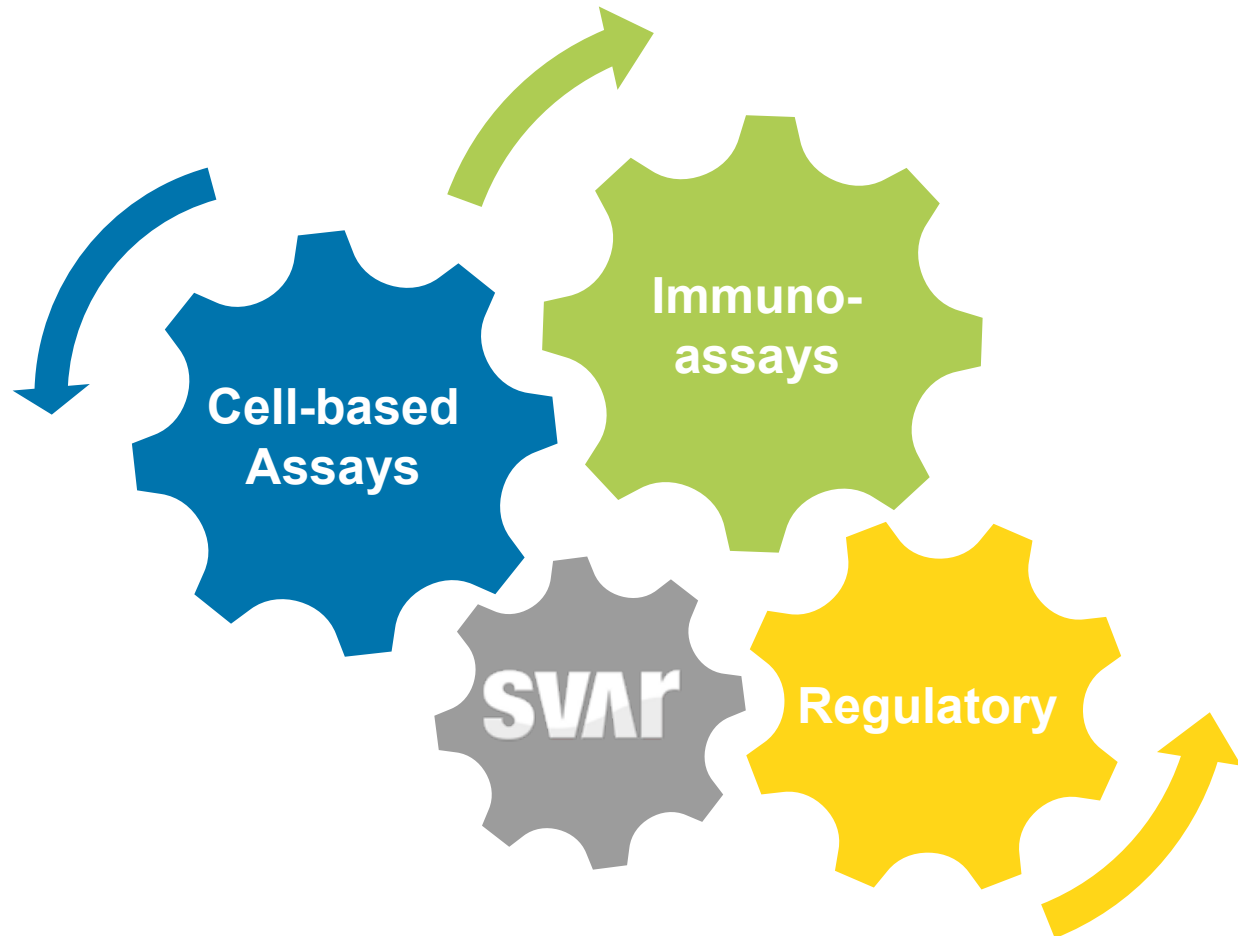
**Therese Segerstein**

Portfolio Director

SVAR LIFE SCIENCE

# YOUR ASSAY SOLUTION PROVIDER

## CORE COMPETENCES



## AREAS OF EXPERTISE

Complement

Immunogenicity

Potency

Neuroimmunology

Autoimmunity



PRODUCTS &  
SERVICES



# Svar's Business Offerings



**SVAR**

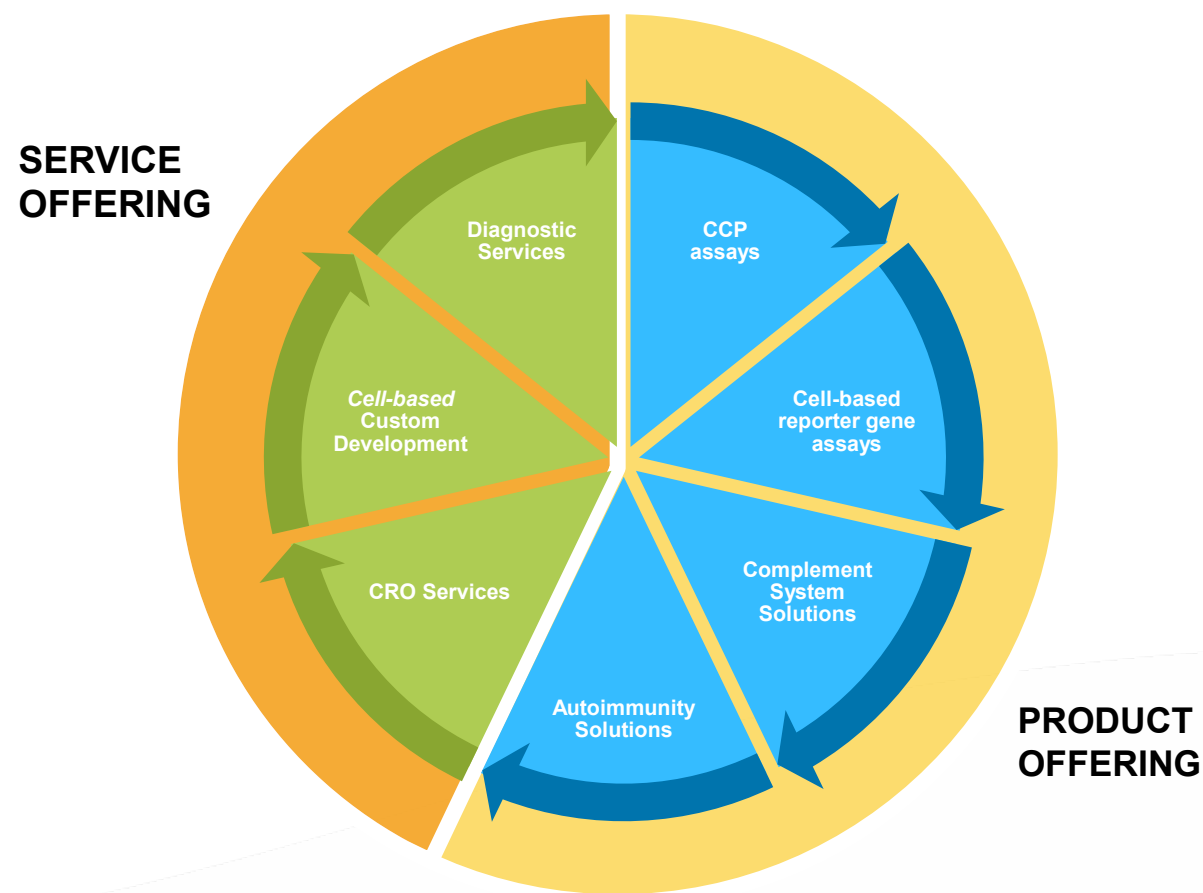
Answers in Life Science



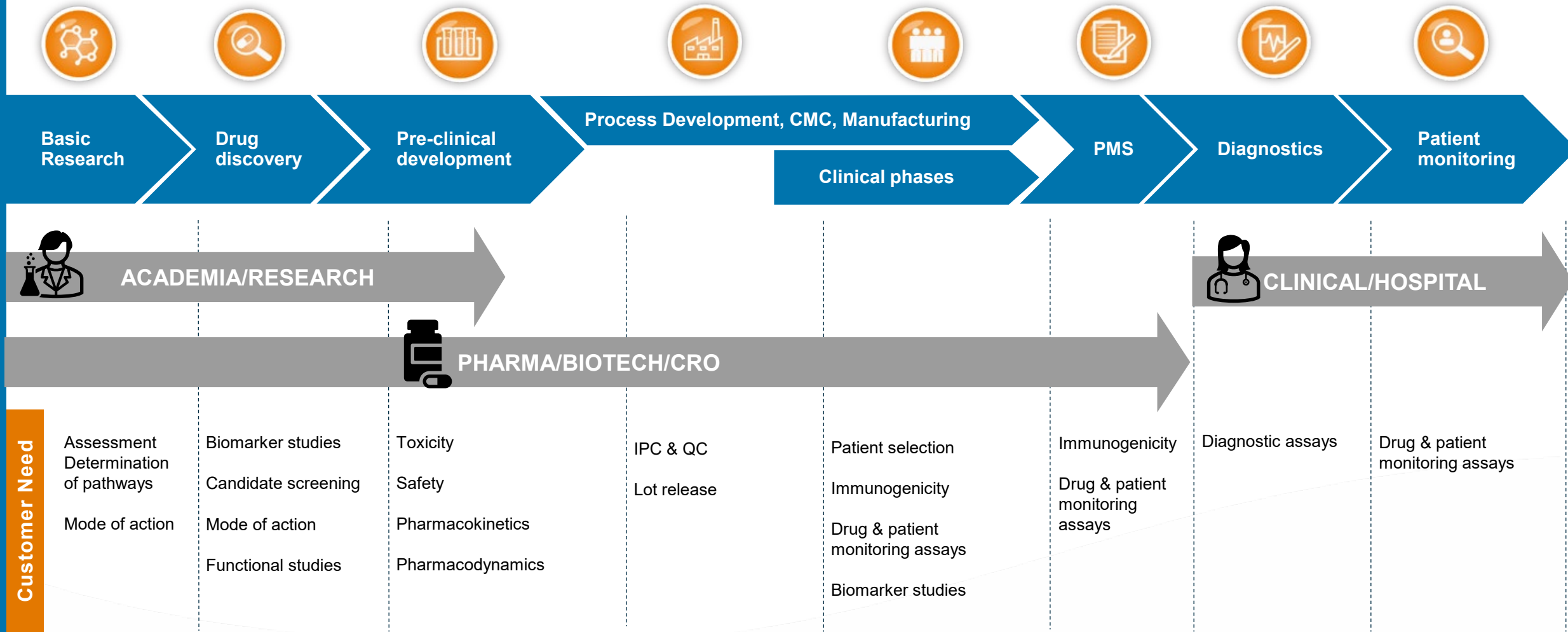
## WHAT WE DO

Simply put, we provide the answers that our customers need throughout the entire drug development value chain – from early discovery through the clinical.

Svar offers a comprehensive product portfolio supporting the development of new drugs and providing tools for patient diagnosis and monitoring within inflammatory diseases.

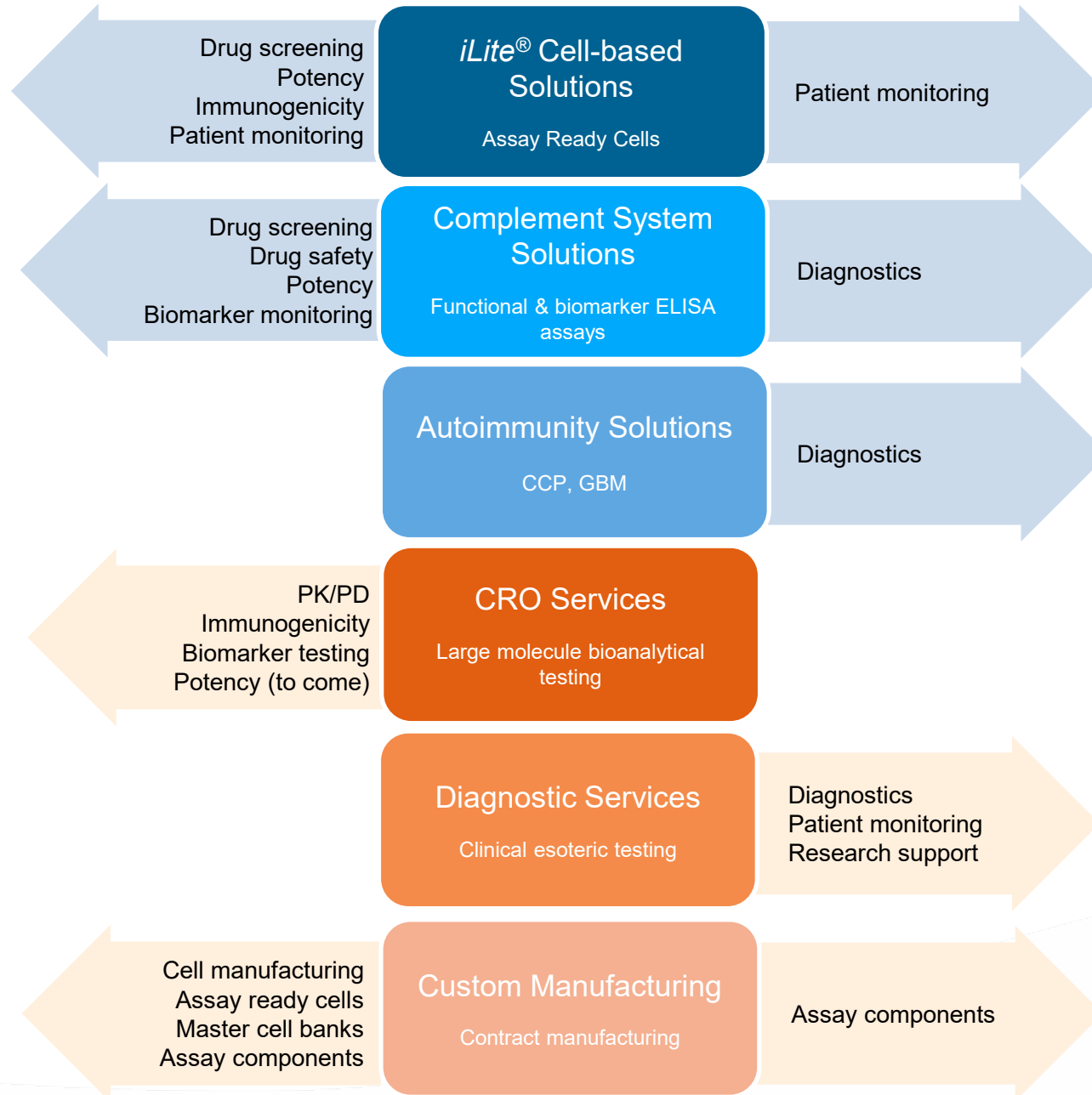


# AT SVAR, WE ENABLE All phases of the Life Science value chain





Pharma



Clinical



Pharma

Discovery  
Pre-clinical testing  
Clinical evaluation  
Manufacturing  
Post-market

**iLite® Cell-based Solutions**

Assay Ready Cells & custom development

**Complement System Solutions**

Functional & biomarker ELISA assays

**Autoimmunity Solutions**

CCP, GBM

**CRO Services**

GLP, GCP Bioanalytical testing

**QC Testing Services**

GMP lot release testing

**Diagnostic Services**

Clinical esoteric testing

Diagnostics  
Patient monitoring



Clinical

## Three product portfolios

### COMPLEMENT SYSTEM SOLUTIONS

Functional & biomarker  
ELISA assays (IVD & RUO)



### iLITE® CELL-BASED SOLUTIONS

Assay Ready Cells, Custom  
development & Cell-based  
Services



### AUTOIMMUNITY SOLUTIONS

Immunoassays for autoimmunity  
Contract manufacturing & OEM



## Combined with three service portfolios

### CRO SERVICES

BIOMARKER DISCOVERY SERVICES (non-GxP)

- Olink® Technology
- Simoa® Technology

BIOANALYTICAL SERVICES (GLP, GCP)

- TK, PK, and PD Assays
- Immunogenicity Assays
- Biomarker Assays (ELISA and MSD)

QC TESTING

- GMP Bioassays
- Potency Testing



### CUSTOM SERVICES

- Custom Bioassay Development
- Assay Ready Cell Services
- R&D Services
- Contract Manufacturing



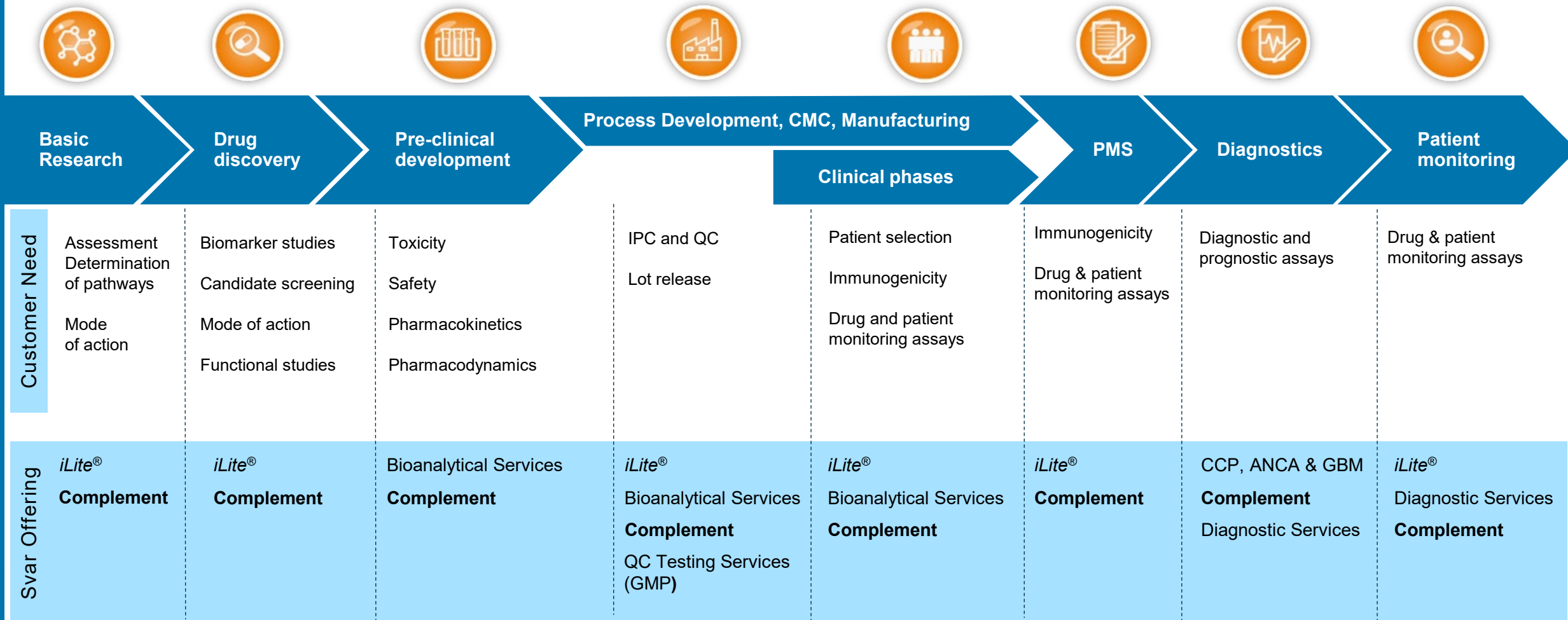
### DIAGNOSTIC SERVICES

- Rare Disease Biomarkers
- Clinical Research
- Therapeutic Drug Monitoring



# Svar's Technologies & Services

## HOW THEY FIT IN THE LIFE SCIENCE VALUE CHAIN





# COMPLEMENT SYSTEM SOLUTIONS

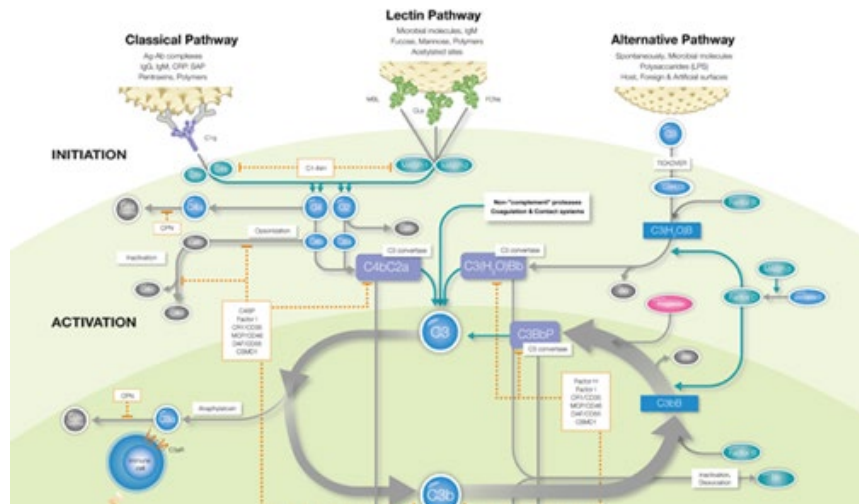
At Svar, we are complementing life science!

Svar is changing the way life science, pharma, and healthcare providers can advance their complement-related testing and assessment needs.

By offering a unique combination of expertise, high-quality products, services, and technology platforms, Svar provides end-to-end and customizable solutions that no other single business can. oiler plate

# Complement System Solutions

## ASSESSING THE INNATE IMMUNE SYSTEM



### WHAT IT IS

Functional assessment assays for all three pathways along with select biomarker assays in simple and accurate ELISA & cell-based formats

- Reduced hands-on-time
- Higher assay robustness

### WHAT IT'S USED FOR

Used by pharma companies, CROs, academics and clinical laboratories. Applications both within drug development and diagnostics as well as research

- Diagnosis of complement deficiencies or over-activation
- Drug candidate screening
- Drug safety measurements
- Assessment of potency (lot release)
- Monitoring of biomarkers in clinical trials

## KEY OFFERING



### PRODUCT PORTFOLIO

#### Functional assays

##### ELISA assays

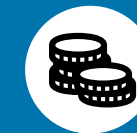
- Classical Pathway
- MBL Pathway
- Alternative Pathway
- Factor P

#### Cell-based assays

- *iLite* C5a
- *iLite* CDC

#### Biomarker assays

- TCC
- C4d
- Factor P



### REVENUE (FY2024)

**56 MSEK**



### GEOGRAPHIC

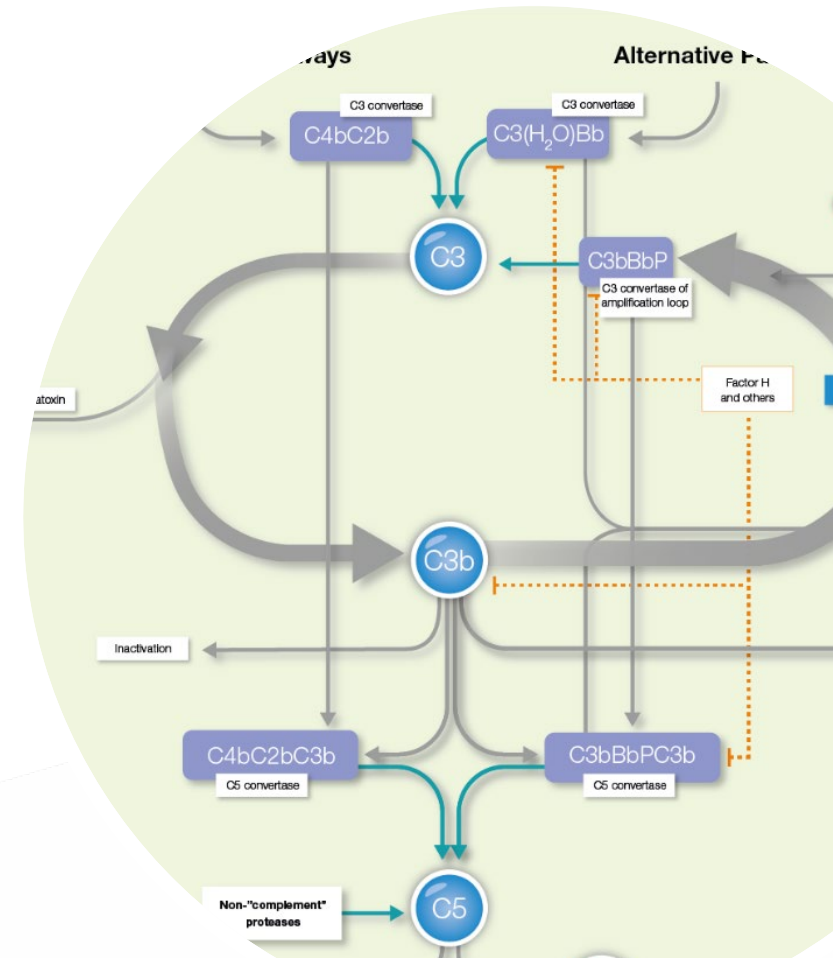
#### COVERAGE

APAC, Europe, North America  
South America

# Key differentiation factors

## Complement Solutions

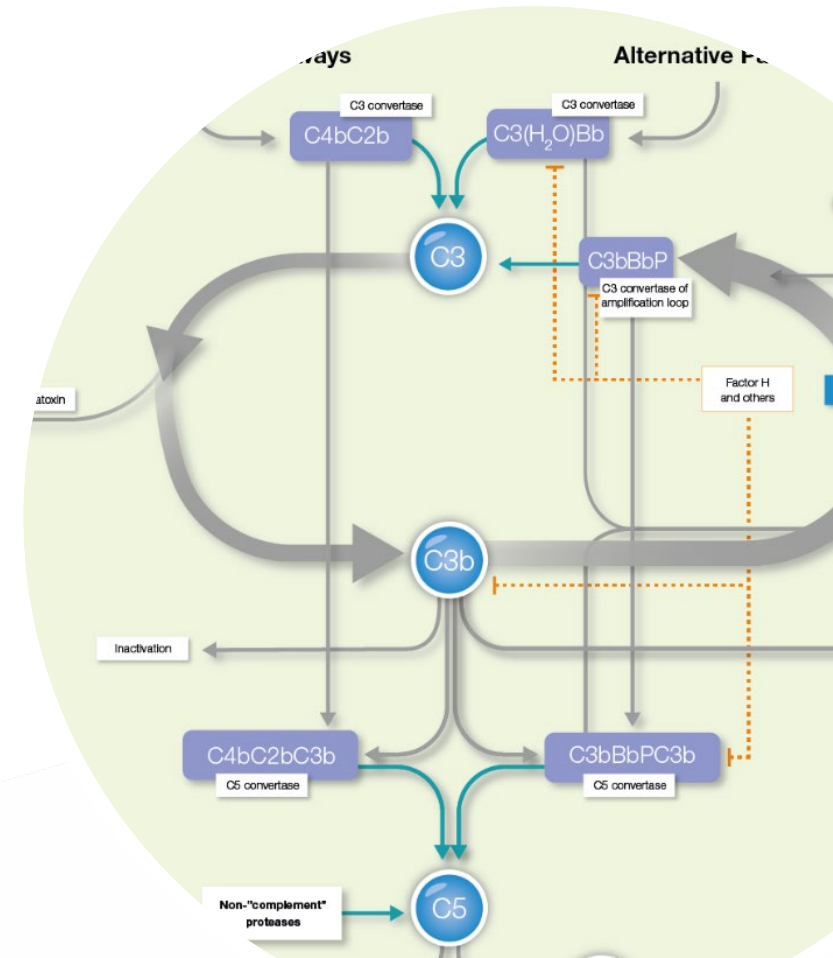
- The only company offering functional ELISAs for all three pathways (human)
  - MBL pathway is patent protected (expiry 2028-10-21)
  - Clinically proven to replace hemolytic assays
- Unique expertise and competence as result of long experience in the area – consulting
- Diverse platforms allow Svar to have a diverse complement offering (next slide)
  - CRO Services and *iLite* are largest synergies
  - Services put ear to the ground regarding market need which can be funneled into R&D product development

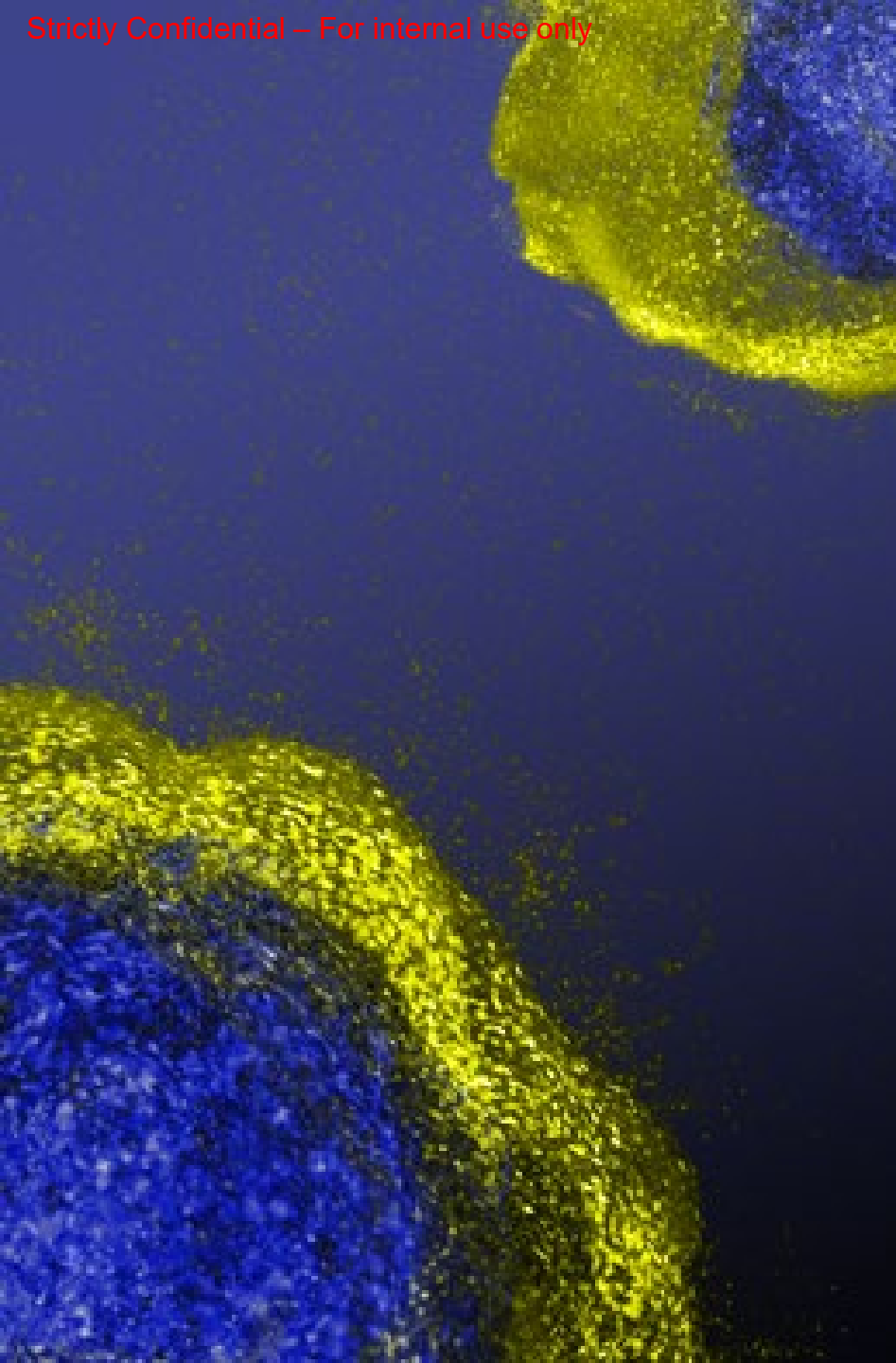


# Typical Customers – How buys these assays? Complement Solutions

## Typical Customers & Use Cases

- **Clinical / Diagnostic Labs**
  - Complement deficiency
  - Complement over-activation
- **Pharma / Biotech**
  - Drug candidate screening
  - Drug safety & mechanism of action
  - Lot release & potency
- **CROs / Research Labs**
  - Functional complement characterization





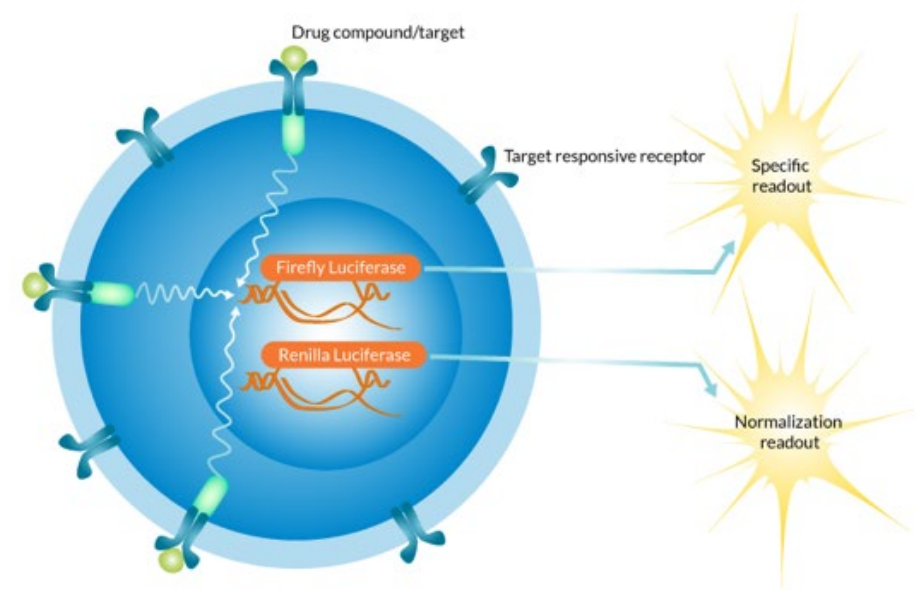
# CELL-BASED SOLUTIONS

As experts in cell engineering and advanced cell-based assay development, we provide proprietary platforms, the advanced iLite technology, and tailored services, empowering clients to navigate complex hurdles with confidence and propelling advancements in their drug development journey.

When standard solutions fall short, we specialize in developing reliable, personalized cell-based assays to meet our customer's testing and assessment needs. Our commitment to responsibility and innovation ensures that we not only cover the entire drug development value chain but also pioneer specific expert areas like Gene Therapy, shaping the future of drug development.

# iLite<sup>®</sup> Cell-based Solutions

## ENABLING EFFICIENT DRUG DEVELOPMENT



### WHAT IT IS

Cell-based reporter gene assay technology

- Robust Assay Ready Format
- Unique Normalization Gene
- Unrivalled Sensitivity and Specificity
- Great reproducibility and accuracy

### WHAT IT'S USED FOR

Used by pharma companies, CROs and clinical laboratories. Applications both within drug development and patient monitoring

- Drug candidate screening
- Assessment of drug potency (lot release)
- Detection of neutralizing antibodies (NAbs)
- Therapeutic drug monitoring

## KEY OFFERING



**ASSAY READY CELLS & CUSTOM DEVELOPMENT**

### SERVICE PORTFOLIO

- Assay Ready Cell Service
- Master Cell Banking
- Custom Assay Development

### PRODUCT PORTFOLIO

- T-Cell Activation Bioassays
- Fc Effector Activity Bioassays
  - ADCP Bioassays
  - ADCC Bioassays
  - Target Cells
- Functional Bioassays
- Gene Therapy Solutions
- CDC Bioassays



**REVENUE (FY2024)**

**43 MSEK**



**GEOGRAPHIC**

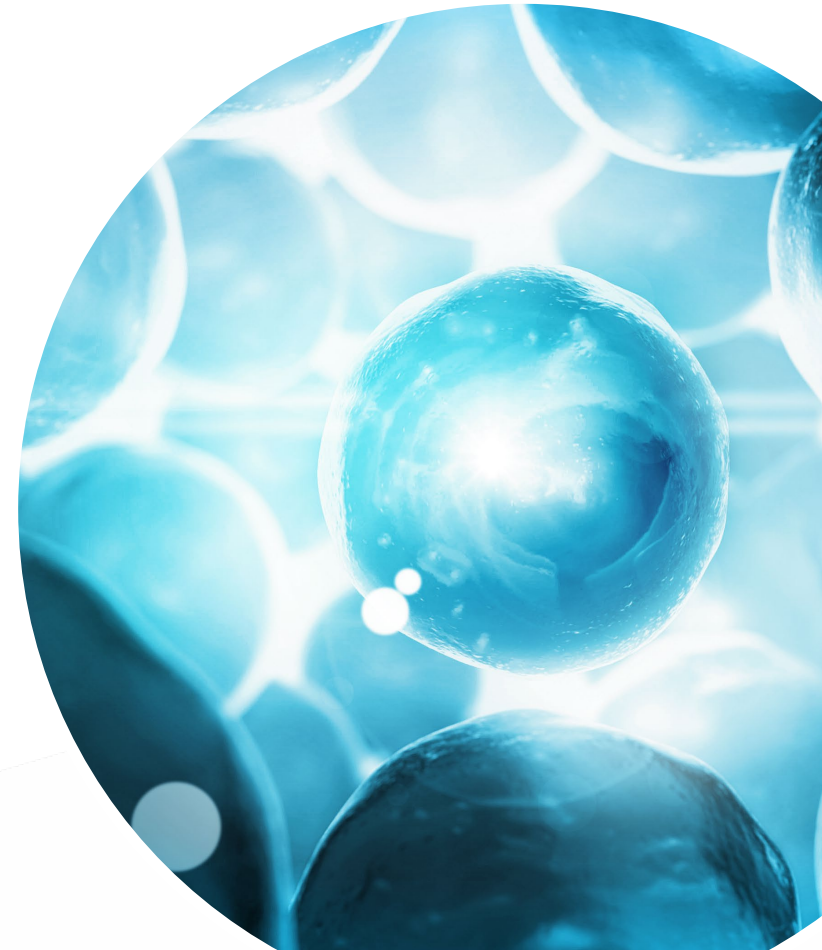
COVERAGE

Europe, North America, APAC

# Key differentiation factors

## *iLite*<sup>®</sup> Cell-based Solutions

- Unique expertise in custom assay development – extremely high success rate
- Innovation driver in value creating features:
  - Specificity – chimeric transcription factor
  - Robustness – assay ready cells & normalization read-out
  - New assay setups - effector & target cells
- OTS products are always either different from leading competitor or better
- Comprehensive offering of OTS products, assay ready cell service, master/working cell banking and custom assay development
- Unique in offering to clinical segment



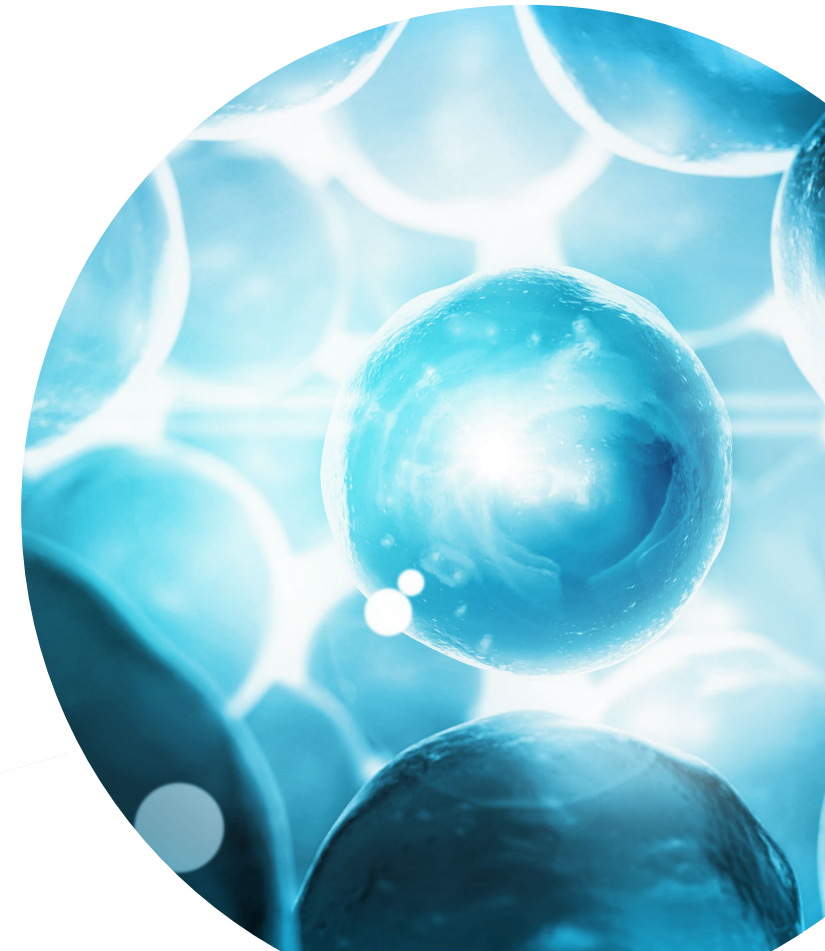
# Typical Customers – How buys these assays?

## *iLite*<sup>®</sup> Cell-based Solutions

The main customer type is a pharmaceutical company that requires a cell-based functional assay in their BIOLOGICAL drug testing; hence, biopharmaceuticals are the target group.

The majority of these biological compounds are antibodies – polyclonal, monoclonal, and engineered to different extents.

- Biopharmaceutical companies working with biological compounds such as therapeutic antibodies and/or recombinant proteins.
- Companies working with biosimilars
- Departments within Analytical Development
- Clinical Diagnostic Labs that perform Therapeutic Drug Monitoring



# AUTOIMMUNITY SOLUTIONS

Our CCP solutions are designed for detecting and semi-quantifying IgG antibodies against CCP. The anti-CCP2 test offers high specificity and sensitivity, making it a reliable tool for early diagnosis and monitoring of Rheumatoid Arthritis (RA).

- The gold standard in anti-CCP testing
- Uses standard ELISA technology
- Detection and semi-quantitation of IgG antibodies against CCP
- High Specificity and Sensitivity
- A Reliable and Accurate toolset for RA diagnosis and follow-up



# Autoimmunity Solutions

## AUTOIMMUNE DIAGNOSTICS



### WHAT IT IS

ELISA assays and antigens for diagnosing autoimmune disorders:

- CCP - gold standard for diagnostics of RA
- GBM – diagnostics of Goodpasture’s syndrome and autoimmune glomerulonephritides
- Contract manufacturing of Calprotectin assays – diagnostics/monitoring of IBD

### WHAT IT’S USED FOR

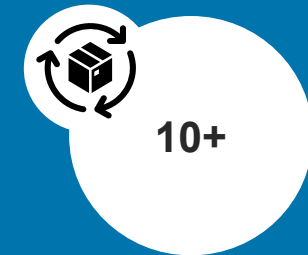
Used by hospital and clinical laboratories as well as large diagnostic platform providers for diagnostics of autoimmune disorders.

Solutions are provided by Svar through:

- Sale of Svar labelled IVD(R) kits to labs, hospitals and clinics
- OEM/reagent sales to diagnostic platform providers
- Contract manufacturing

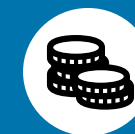
## KEY FIGURES

### PRODUCT PORTFOLIO



### Products, services & licensing

- CCP assays & reagents
- GBM antigen
- Contract manufacturing of calprotectin assays



### REVENUE (FY2024)

94 MSEK



### GEOGRAPHIC

COVERAGE

APAC, Europe, North America  
South America

# What is CCP

## CLINICAL USE:

A CCP antibody test is a diagnostic blood test that helps doctors confirm or rule out RA. It involves drawing a blood sample from a vein with a small needle, which experts then analyze in a laboratory.

Other names include:

- Citrulline antibody
- Cyclic citrullinated peptide antibody
- Anticitrullinated peptide antibody (ACPA)



# Application Areas



## CLINICAL APPLICATIONS

CCP assays are primarily used in the clinical diagnosis of RA. They help in early detection and predicting disease progression

The presence of anti-CCP antibodies is included in the ACR/EULAR criteria for diagnosing RA.



## RESEARCH APPLICATIONS

In research, CCP assays are utilized to study autoimmune diseases and develop new diagnostic markers and therapeutic targets.

They play a significant role in understanding the pathogenesis of RA and other related conditions

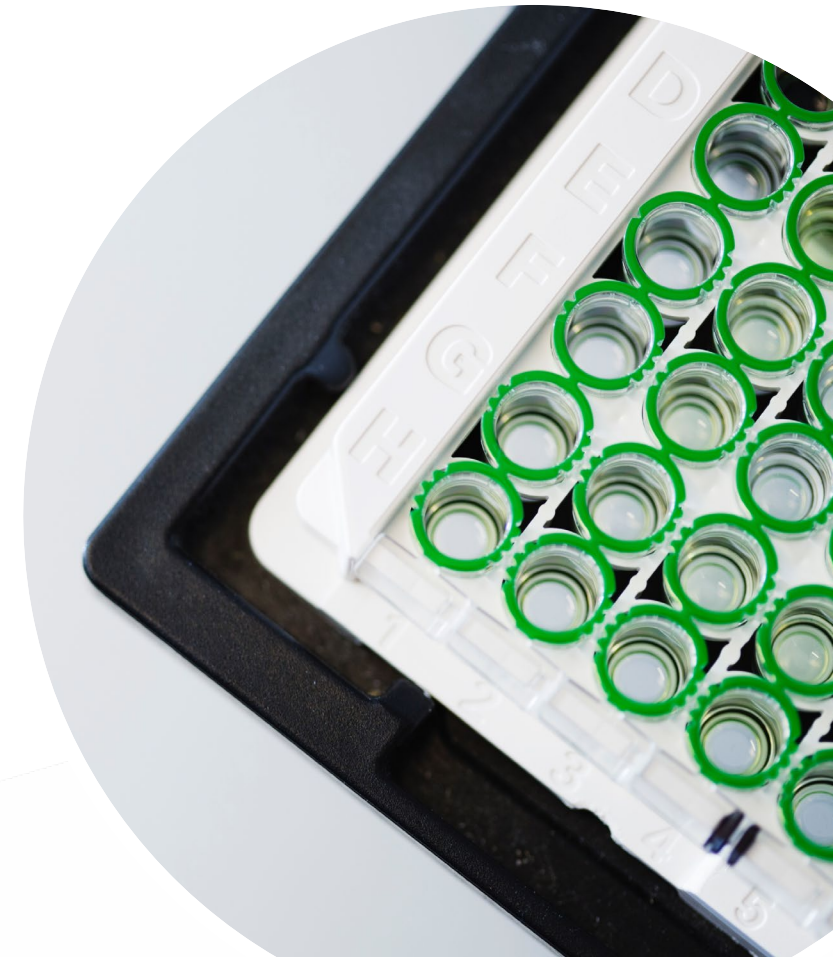
# CCP Portfolio Overview

The Svar CCP portfolio consists of enzyme-linked immunosorbent assay (ELISA) for the detection and semi-quantitation of IgG antibodies against Cyclic Citrullinated Peptides (CCP).

## CCP Product Portfolio

IMMUNOSCAN CCPlus® [RA-96 PLUS]

IMMUNOSCAN CCPlus® - RUO [RA-96 PLUS RUO]



# Typical Customers – How buys these assays?

## Legacy Solutions

### **Hospitals and Clinics:**

These institutions are primary users of CCP assay products for diagnosing and monitoring RA in patients. They require reliable and accurate diagnostic tools to improve patient outcomes.

### **Diagnostic Laboratories:**

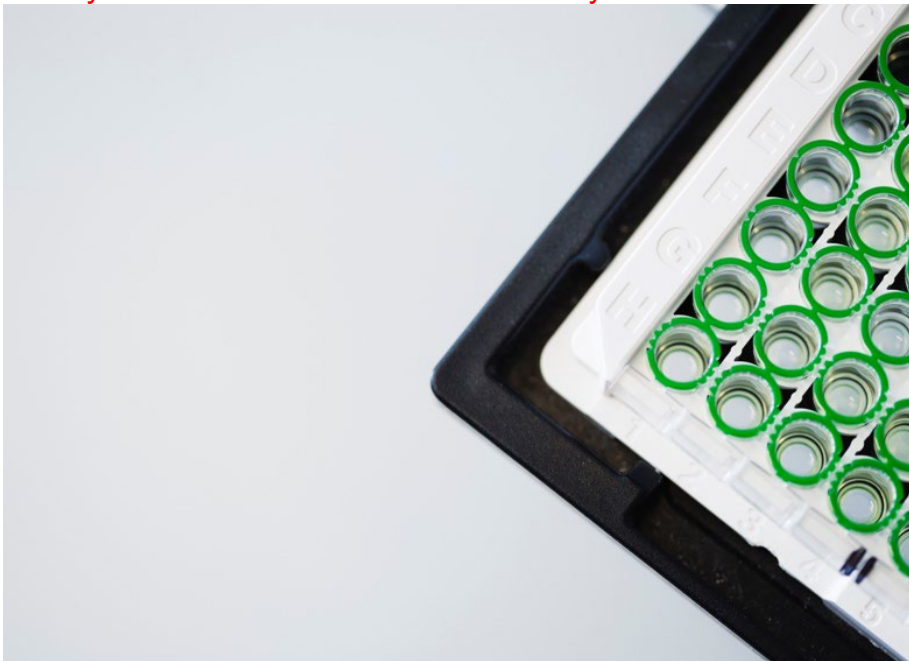
Laboratories perform a high volume of diagnostic tests and need assays that offer high throughput, precision, and ease of use. CCP assays are essential for early and accurate RA diagnosis.

### **Research Institutions:**

These organizations use CCP assays for studying autoimmune diseases and developing new diagnostic markers and therapeutic targets. They require high-quality, validated assays for their research.

### **Pharmaceutical Companies:**

Companies involved in developing RA treatments use CCP assays in clinical trials to monitor disease progression and treatment efficacy. They need assays that provide consistent and reliable results.



# Competitor Information

COMPLEMENT FOCUS

**SVAR**

Answers in Life Science



# Complement Market

## — THREE COMPETITOR TYPES



Clinical IVD Specialists

Strong branding  
Limited pathway breadth



RUO Reagent Specialists

Large catalogs  
Less standardization,  
limited functional focus



Large Life Science Suppliers

Broad portfolios  
Complement is rarely a core focus

# Competitor analysis

## METHODS IN USE

### **Clinical Segment**

- Automated platforms (Liposome Immunoassays / Multiplex ELISA readers)
- ELISA
- Haemolytic assays













### **Pharma Segment**

- ELISA
- Haemolytic assays
- Automated platforms and multiplexing
- Assays compatible in animal models

### **Academic Segment**

- All of the above
- Homebrew assays of various types

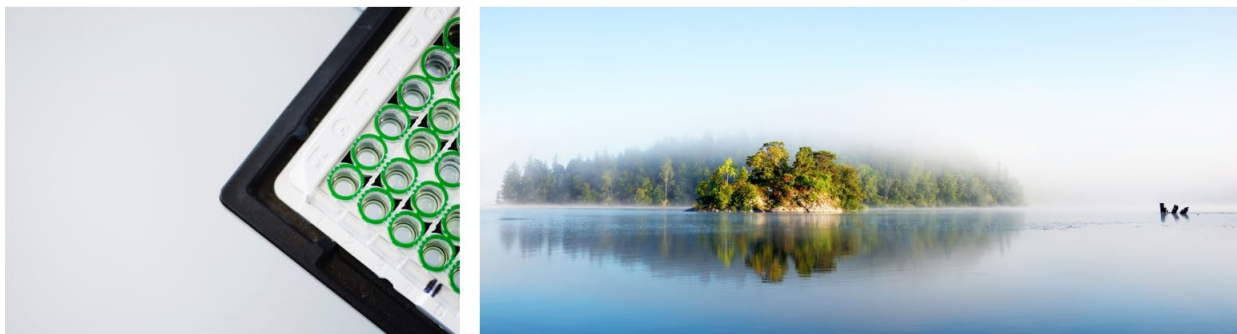
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COMPLEMENT PRODUCTS	
Functional	Quantitative
	
	
	
	
	
	
	
	

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# Objection handling

- theme for one of the Workshop tomorrow











Objection handling

Welcome to the “war room”

**SVAR**

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CELL-BASED SOLUTIONS	
Products	Services
	
	
	
	
	
	

# Takeaways for You

- Svar offers integrated solutions across the life science value chain with good insights into the challenges within drug development and solutions that fits here
- We have a strong diagnostic and clinical legacy throughout, putting innovative solutions as well as the IVD parts of the complement portfolio
- We have strong differentiation in complement and cell-based assays.
- And we combine products and services in a way that is quite unique in the market.





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Answers in Life Science