

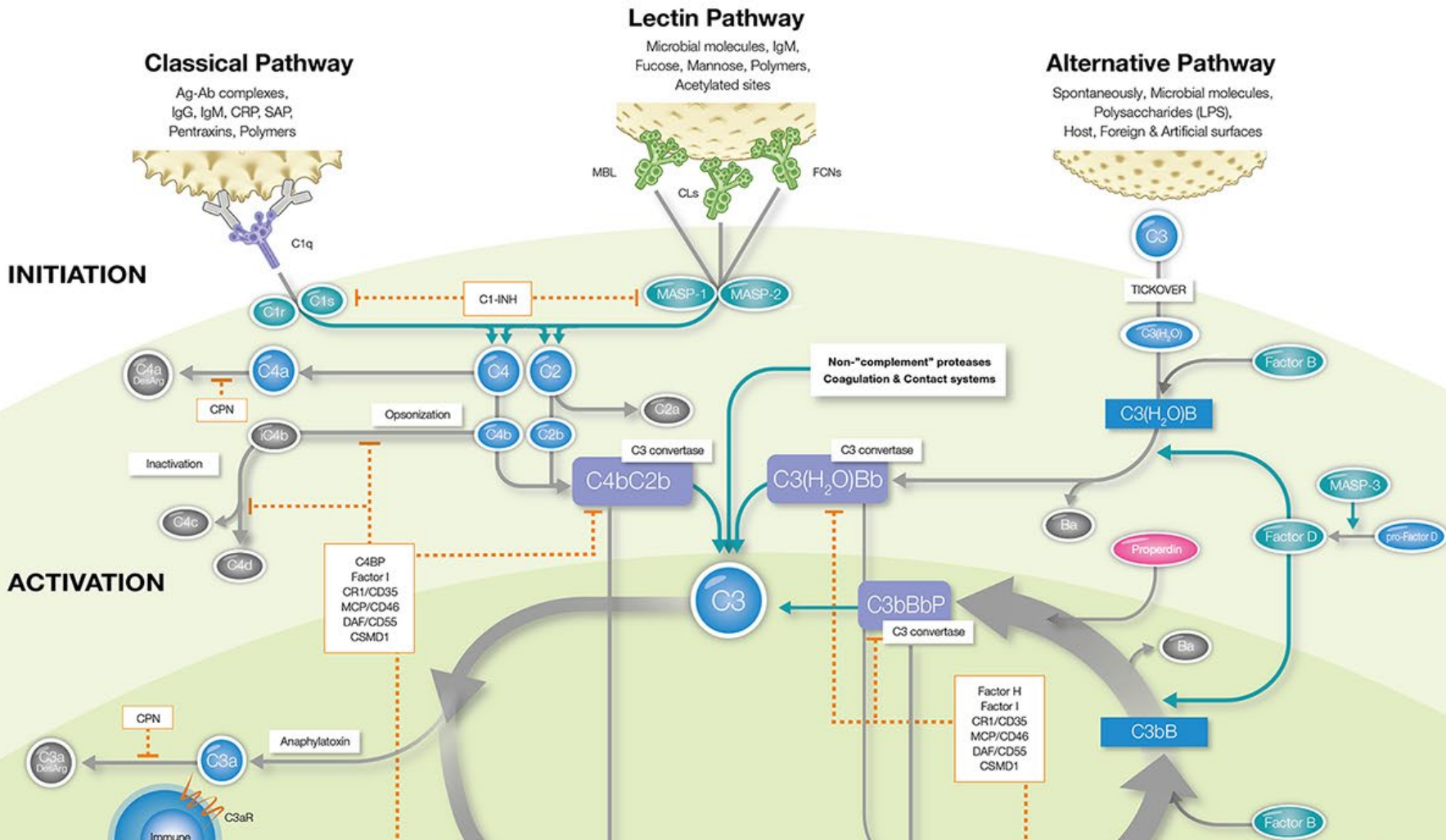
Immunoassays

Pipeline, Trends, & Insights

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Complement & Immunoassay solutions
2026-04-14

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Answers in Life Science

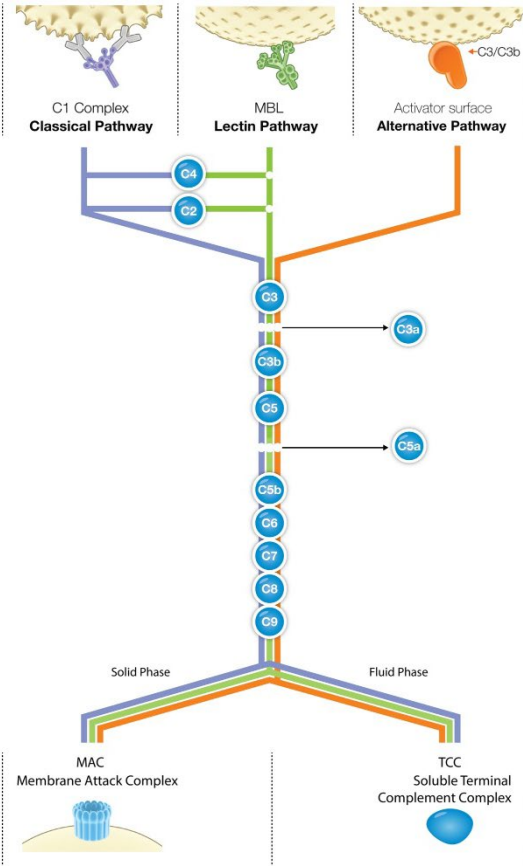




Complement in the 21st century

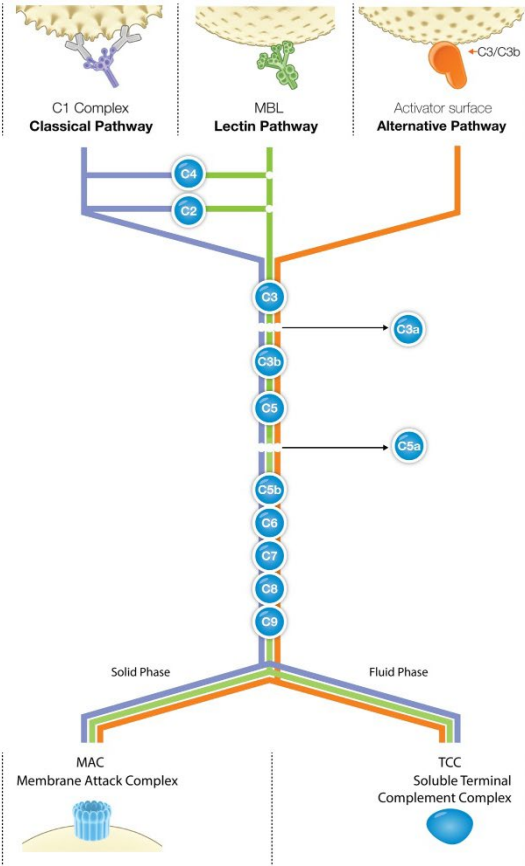


The Complement System



- Three characteristic pathways of initiation
- Converge at “C3-level”
- Amplification loop independent on path
- Signaling molecules that “leave the cascade”
- Terminal Complement Pathway (TCC, MAC, C5b-9)

The Complement System



- Signal rocket for inflammation (anaphylatoxins)
- Tag pathogens/apoptotic cells for phagocytosis (opsonins)
- Neutralise pathogens through lysis (MAC)

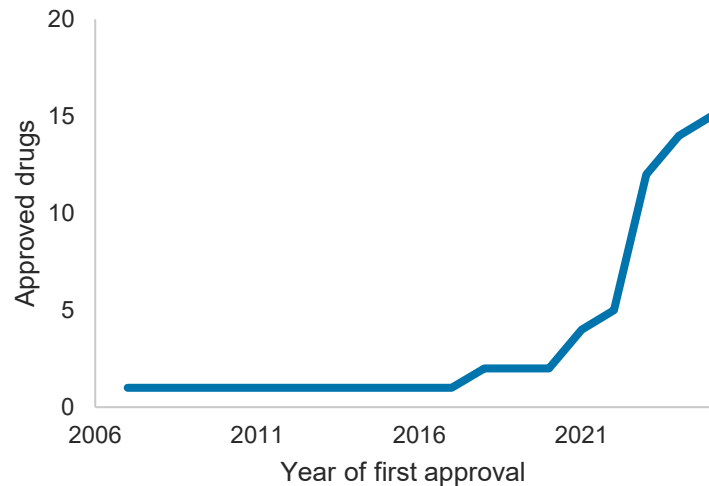


“As complement therapeutics expand, complement diagnostics are becoming essential in clinical care and drug development.”

The advent of complement targeting drugs

- Eculizumab (Soliris)
 - **1999** First in Human trials
 - **2003** Orphan designation for PNH
 - **2007** Approval for treatment of PNH
 - **2009** Orphan designation for aHUS
 - **2011** Approval for treatment of aHUS
 - **2014** Orphan designation for Myasthenia Gravis
 - **2017** Approval for treatment of Myasthenia Gravis
 - **2019** Orphan designation for NMOSD
 - **2023/2024** Eculizumab biosimilars authorised

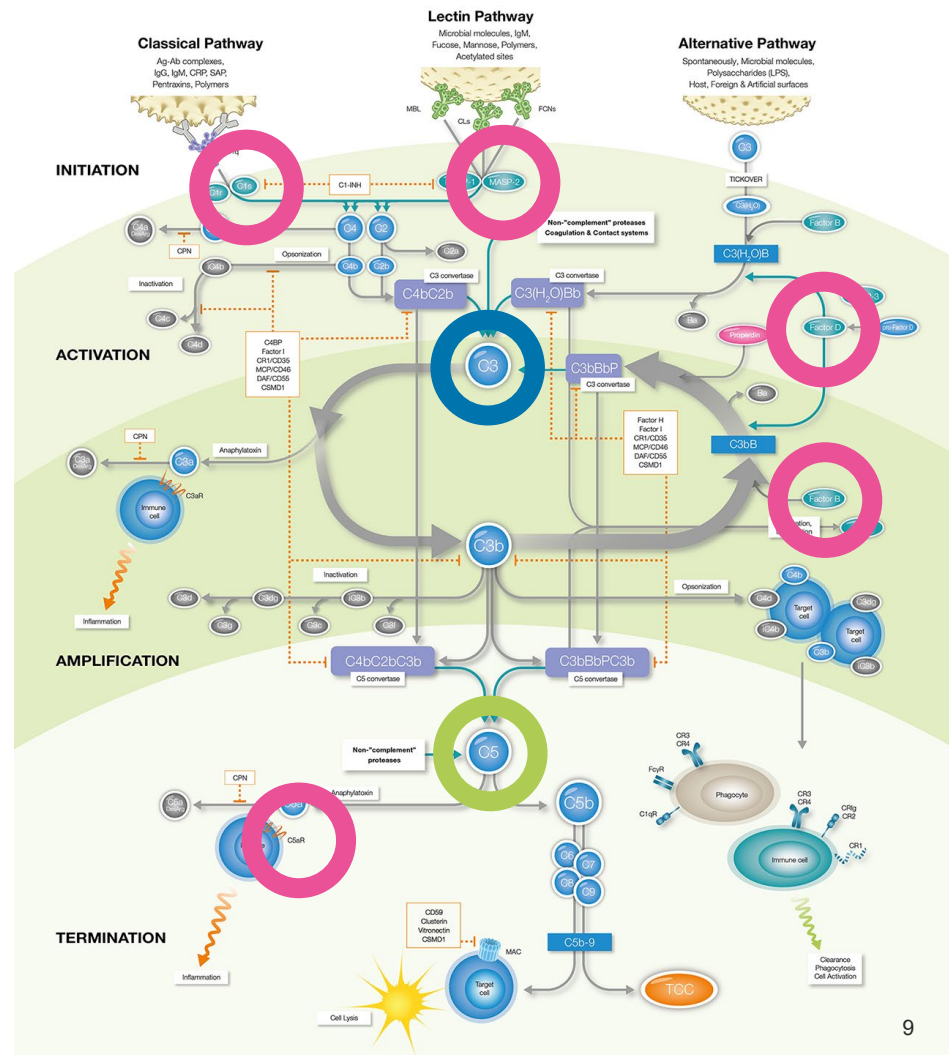
- **2026** >20 approved or late-stage drugs targeting complement components



Extension of targets

Complement is a critical part of our immune system;

- Initial target C5
- Expansion to C3
- Further specificity with
 - C1,
 - C5aR1,
 - MASP-2,
 - FB
&
 - FD

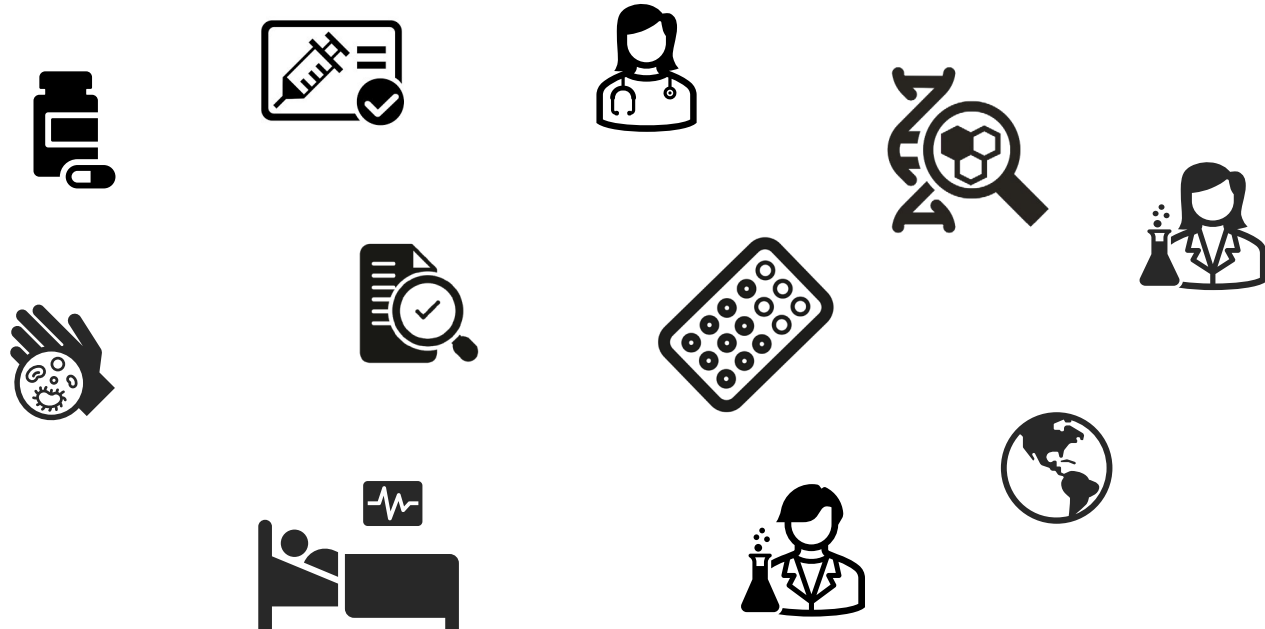


Complement testing trends in different market segments



Spotting the Trends in Complement Testing

How does it all fit together?



Spotting the Trends in Complement Testing

How does it all fit together?



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Clinical segment



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Shifts in clinical complement testing

There is an increasing awareness for complement

- Therapeutic intervention
- Expansion into new labs
- Expansion into new fields of medicine
 - Hematology
 - Autoimmune
 - Nephrology
 - Inflammatory disorders
 - Oncology
 - Neurology
 - Transplantation



Shifts in clinical complement testing

There's been a shift in complement analysis

- Historically, functional CP & AP, along with biomarkers C3 & C4
- Increasingly WIESLAB® functional ELISAs, activation biomarkers (C5b-9, Bb, C4d, C5a etc.) and genetic analysis
- Emerging needs
 - Monitoring of patients on complement targeting therapeutics
 - Stricter regulatory environment



Positioning

Where to play:

Expanding efforts to cover “emerging” areas;
Remember that clinicians order the test.

Lean into your strengths:

Svar have clearly expressed our intent to ensure complete IVD-R compliance for current IVD products.

Feed-back-loop:

Feed back insights to help Svar adapt to your needs.



Pipeline

Ongoing:

Significant effort to ensure IVD-R certification of current IVD portfolio.

Evaluating:

Expansion of selected parts of RUO portfolio into IVD.

Future:

Expanding RUO portfolio with products that may meet emerging clinical needs.



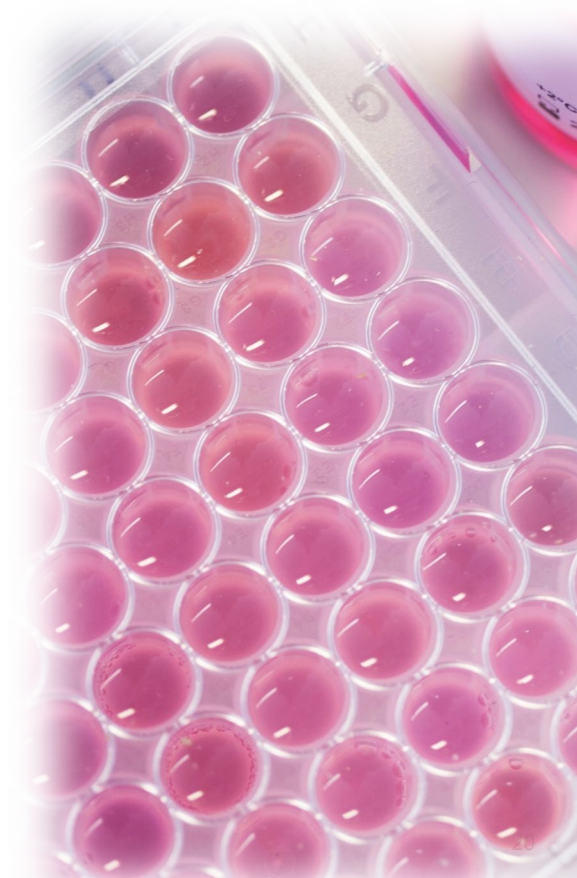
A hiker with a backpack is seen from behind, walking on a dirt trail through a vast, open landscape of rolling hills and mountains under a clear blue sky. The scene is bathed in warm, golden light, suggesting late afternoon or early morning. The hiker is positioned in the middle ground, slightly to the left of the center. The foreground shows the texture of the dirt path and sparse vegetation. The background features distant mountain ranges and a clear horizon.

Complement targeting Pharma segment

Complement testing in Pharma

There is an increasing complexity in testing

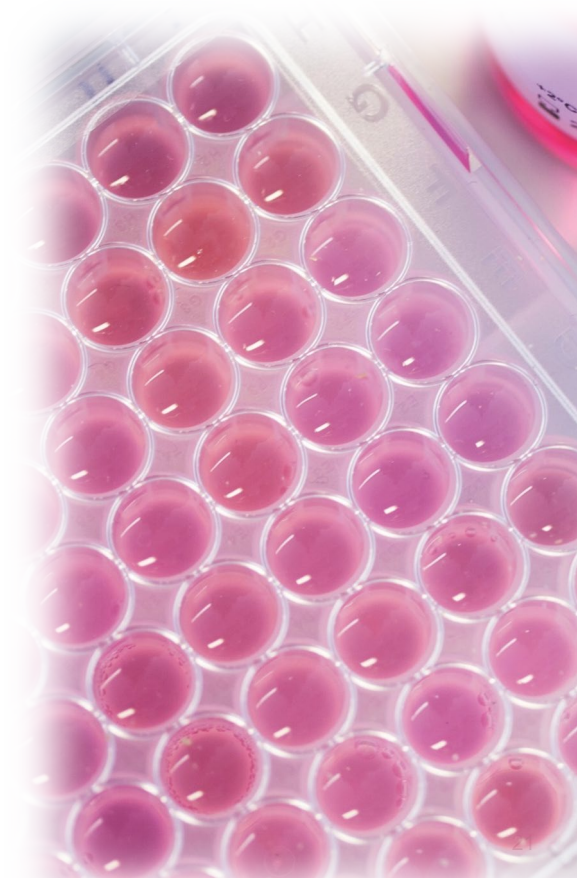
- Expansion of therapeutic targets
 - No size fits all
 - Read-out based on “close-to-target” analyte
- Cost savings in RD&I
 - Outsourcing trends
- Geographical and regulatory shifts
 - Clinical trials by region
 - Functional testing, MoA, & Potency

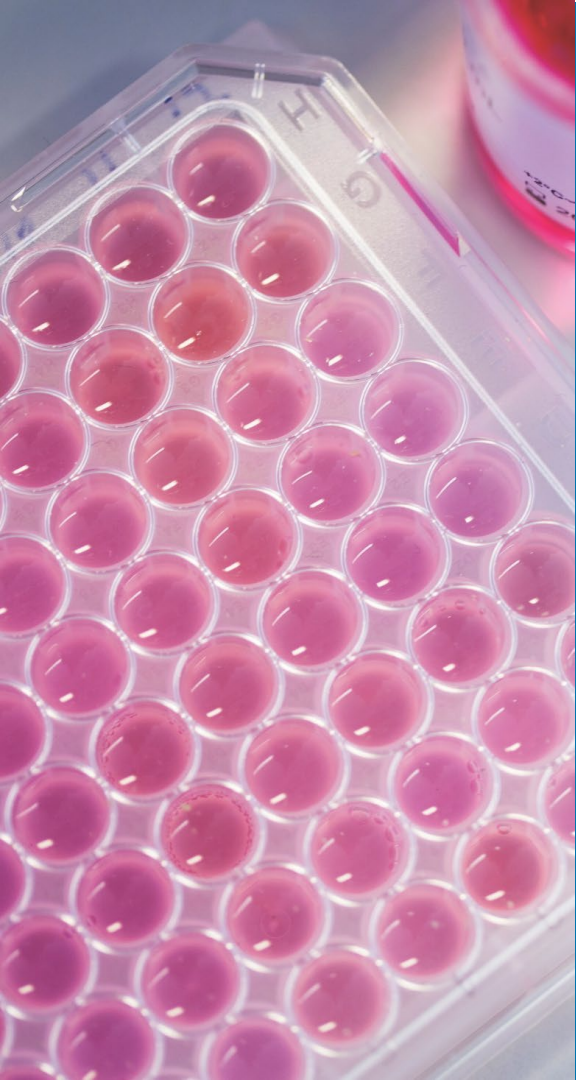


Shifts in clinical complement testing

There's been a shift in complement analysis

- Monitoring pharmacodynamics
- High throughput & standardised
Challenges to be met:
 - Model systems closer to *in vivo* conditions
 - Relevant read-out
 - Regulatory trends uncertainty
- Biosimilars targeting complement





Positioning

Where to play:

Expand on existing networks in pharma, monitoring biosimilars actors & maintain contacts in different departments;

Remember that different stages have different decision makers.

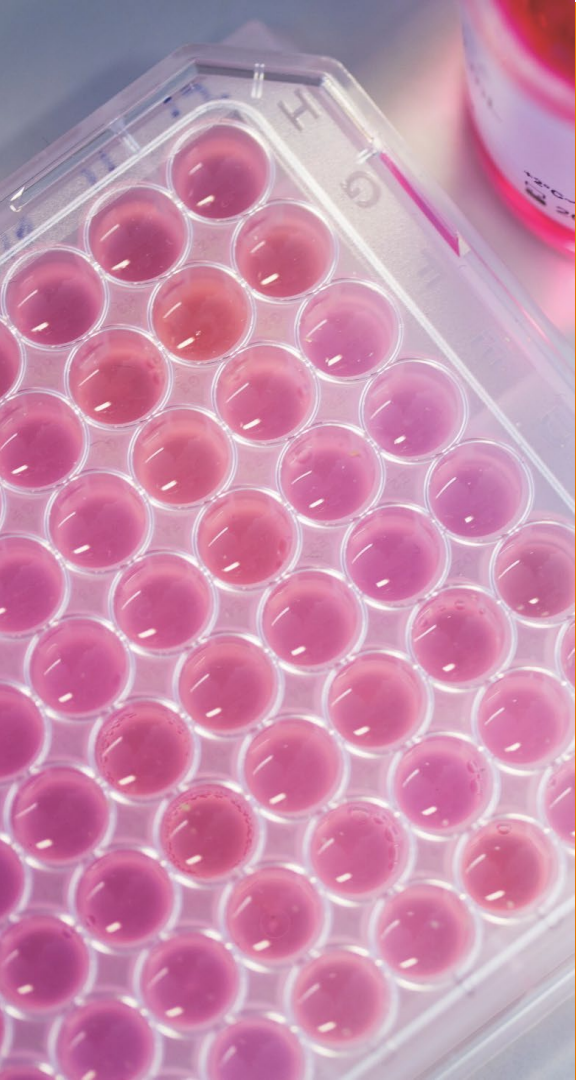
Lean into your strengths:

- Functional assessment with gold standard assays.
- High quality products with IVD equivalents*.
- Versatile solutions in the Svar portfolio.

Svar offers a support structure in complex sales processes.

Feed-back-loop:

Feed back insights to help Svar adapt to your needs.



Pipeline

Ongoing:

Expansion of RUO-portfolio with biomarker assessment focus, including high quality core components and activation products.

Evaluating:

Development of support functions for specific customer applications.

Future:

Novel assay formats to meet emerging needs in complement targeting drug assessment.

Non-complement targeting Pharma & MedTech segments

What's this?

Non-complement targeting Pharma

All drugs not targeting complement that could cause unintentional activation:

- Antibody based therapeutics
- Therapeutic enzymes
- Liposomal drugs / LNPs / Nanomedicines
- Gene therapy vectors
- Pegylated drugs



MedTech

Devices and materials that could activate complement when in use:

- Hemodialysis membranes and tubing
- Cardiopulmonary bypass circuits
- Vascular stents / grafts / artificial valves
- Biosensors
- Novel coating materials



Complement testing for safety assessment

Assessing complement activation risk

- Complement activation is a predictable off-target risk
 - Many drugs interact with complement
 - Unintentional activation is a significant safety concern
 - Regulators expect mechanistic understanding
- Testing is relevant in:
 - Preclinical safety studies
 - Early clinical development
 - Re-evaluation after change / expansion



Positioning

Where to play:

All pharma with specific focus on pharma projects with biologics candidates. Principle investigators and clinical managers in preclinical and early clinical development

Lean into your strengths:

Functional and biomarker assessment with high quality products and versatile solutions in the Svar portfolio.

Svar offers a comprehensive offering to support the segment's needs.

Feed-back-loop:

Feed back insights to help Svar adapt to your needs.

Pipeline

Ongoing:

Product and service offerings for AAV gene therapy, NAb, TAb, and AAV-induced complement activation assessment;

New product launch!

Specifically targeted development for activation biomarkers.

Evaluating:

Support functions and bundling recommendations in line with regulatory recommendations for this segment.

Future:

Novel assay formats to address general activation assessment needs.

Take home message

- Complement assessment is growing to catch up to the past decades of development.
- There are feed-back loops between market segments.
- Poor communication between customer's departments lead to lost opportunities. Diversify contacts!
- Svar is meeting emerging needs with:
 - High quality assays with a legacy
 - Targeted priority to expand RUO portfolio
 - RD&I to develop assays for the future
 - Knowledge support to meet needs



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Answers in Life Science

Thank you for listening!

Feel free to reach out with your questions



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LET'S CONNECT!