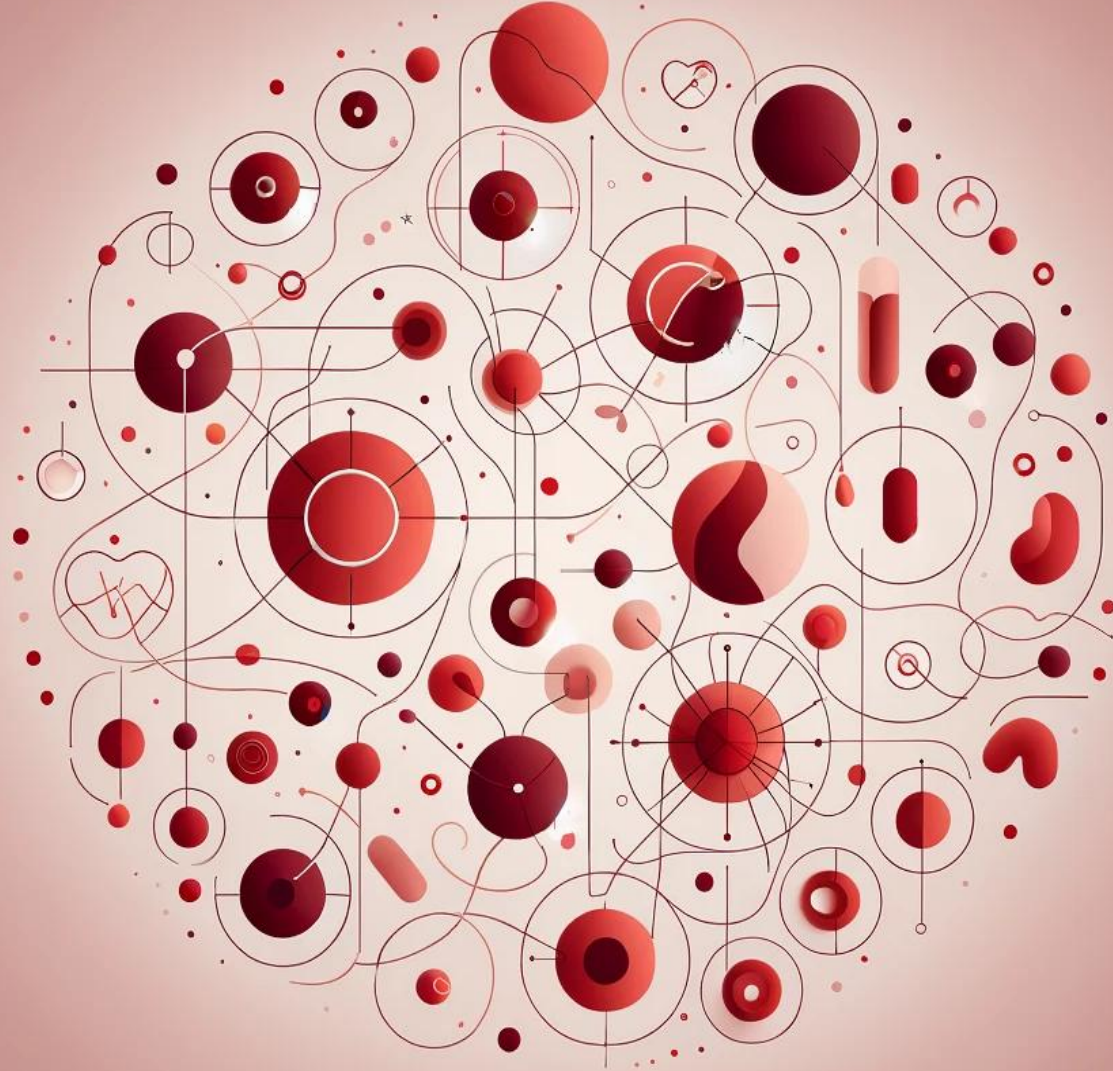


FSCDR 2026 Preview – Clinical



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FSCDR 2026 – New Trends in SCD Treatment Strategy (1/3)



- **Hemoglobin biology will remain a central competitive battleground**

- FSCDR 2026 will feature multiple hemoglobin-focused strategies, including etavopivat, osivelotor, pociredir, voxelotor registry analyses, and low-dose sublingual curcumin. The strategic question will be whether hemoglobin improvement, HbF induction, HbS polymerization inhibition, and red blood cell sickling kinetics can be linked to clinically meaningful outcomes beyond laboratory improvement



- **Etavopivat will move from anemia correction toward disease-modification positioning**

- Novo Nordisk will present HIBISCUS 2 Phase 3 trial-in-progress data, HIBISCUS Kids Phase 1/2 adolescent safety and efficacy findings, and a real-world study of hemoglobin and end-organ damage. The key question will be whether PKR activation can support a broader organ-protection and long-term disease-management narrative in SCD





- **Polymerization inhibition will face renewed scrutiny**

- FSCDR 2026 will include osivelotor Phase 2 dose-finding and extension data and voxelotor RETRO/PROSPECT registry analyses. The competitive question will be whether next-generation or legacy polymerization-related approaches can rebuild confidence around safety, durability, and real-world effectiveness



- **Gene therapy will shift from clinical efficacy to implementation readiness**

- The congress will feature Exagamglogene autotemcel / Exa-Cel real-world benchmarking and a LYFGENIA patient journey product theater. The strategic issue will be whether gene therapy differentiation will increasingly depend on treatment-center readiness, patient navigation, nursing education, and real-world outcomes rather than pivotal trial efficacy alone



- **Biomarkers and endpoints will become a development-rate limiter**

- The CSL / Agios symposium will focus on biomarkers as endpoints, FDA biomarker qualification pathways, patient-centered endpoints, and chronic pain as a clinical trial endpoint. This will matter because future SCD studies will need stronger endpoint logic across hemoglobin, pain, VOCs, organ damage, and patient-reported outcomes



- **Pain management will be reframed as multiple distinct development questions**

- FSCDR 2026 will address buprenorphine-based inpatient analgesia, sPLA2 during VOE and ACS, opioid pharmacogenomics, chronic pain endpoints, and SickieFit exercise feasibility. The field will need to separate acute VOE biology, chronic pain measurement, opioid optimization, and non-pharmacologic intervention strategies





Key Sessions To Watch (1/2)

Date	Session Title (short)	Type	Author / Institution	Why Watch
5 June 2026	Biomarkers and endpoints in SCD	Special symposium	Patrick C. Hines / Functional Fluidics; Donna Whyte-Stewart / FDA	This session will frame how biomarkers, surrogate endpoints, and patient-centered endpoints may influence SCD trial design
5 June 2026	Anumigilimab Phase 2 TRANSCENDING design	Poster	Paul M. Shore / CSL Behring	This will show how CSL is entering inflammatory modulation in SCD and how safety is being prioritized
5 June 2026	DISC-3405 Phase 1b in SCD	Poster	Susanna Curtis / Mount Sinai	This early clinical readout will clarify whether DISC-3405 has a definable SCD development rationale
5 June 2026	CSL889 RHEMEDY study design	Poster	Paul M. Shore / CSL Behring	This will indicate how CSL is shaping a VOC-focused strategy across adults and adolescents
5 June 2026	Voxelotor RETRO/PROSPECT registries	Poster	Nirmish Shah / Duke	These registry analyses will provide important context for real-world polymerization-inhibitor safety and effectiveness
6 June 2026	Osivelotor Phase 2 dose-finding	Oral	Santosh L. Saraf / University of Illinois Chicago	This will be the central readout for whether next-generation polymerization inhibition can remain commercially and clinically investable
7 June 2026	Exa-cel real-world benchmarking	Oral	Bettina Teng / HCA Florida JFK / University of Miami	This will benchmark real-world exa-cel outcomes against CLIMB trial expectations
7 June 2026	Hemoglobin and end-organ damage	Oral	Elnara Fazio-Eynullayeva / Novo Nordisk	This will support Novo's effort to link hemoglobin change with organ-risk outcomes





Key Sessions To Watch (2/2)

Date	Session Title (short)	Type	Author / Institution	Why Watch
7 June 2026	HIBISCUS 2 etavopivat Phase 3	Oral	E. Leila Jerome Clay / Novo Nordisk	This will show how Novo is framing adult and adolescent Phase 3 development for etavopivat
7 June 2026	Pociredir Phase 1b PIONEER	Oral	Sheinei S. Alan / Inova Adult Sickle Cell Program	This will clarify pociredir safety, HbF, hemoglobin, and hemolysis signals in severe SCD

Industry-Sponsored Sessions & Focus Areas – FSCDR 2026





FSCDR 2026– Competitive Landscape at a Glance (1/2)

Name	Sessions	Companies / Assets	Why It Matters
PKR activation and hemoglobin biology	3	Novo Nordisk / etavopivat	Novo will test whether hemoglobin improvement can be linked to broader disease-modification and organ-protection claims
HbS polymerization inhibition	2	Osivelotor; voxelotor	Polymerization inhibition will need to address confidence gaps created by voxelotor-related safety concerns.
HbF induction / epigenetic modulation	1	Pociredir	Pociredir will need to show whether HbF induction can remain competitive in hydroxyurea-intolerant or unresponsive severe SCD
Inflammation and VOC biology	3	CSL / anumigilimab, CSL889; sPLA2	CSL and academic investigators will frame inflammatory pathways as actionable targets in VOC and ACS biology



FSCDR 2026– Competitive Landscape at a Glance (2/2)

Name	Sessions	Companies / Assets	Why It Matters
Gene therapy implementation	3	Exa-cel; LYFGENIA; lovotibeglogene autotemcel	Post-approval differentiation will increasingly depend on access logistics, nursing readiness, and real-world outcome benchmarking
Biomarkers and endpoint strategy	5+	CSL, Agios, Functional Fluidics, FDA, VCU	Biomarker qualification and pain endpoints will shape how future SCD trials define clinical benefit
Screening and care access	4+	Gazelle platform; RECIPE linkage coordinators; UAB nurse education; NYC stigma intervention	Operational models will be presented as levers to improve diagnosis, retention, and therapy uptake



Key Industry-Sponsored Sessions at FSCDR 2026 (1/3)

✓ • **CSL / Agios Pharmaceuticals:**

- Focus Areas: Biomarkers, Endpoint Strategy & Patient-Centered Outcomes in SCD
- Sessions will examine biomarker qualification, FDA approval pathways, patient-centered endpoints, chronic pain as a clinical trial endpoint, and industry perspectives on how endpoints may shape future SCD trial design

✓ • **Agios Pharmaceuticals / Fulcrum Therapeutics:**

- Focus Areas: Grant Development, Research Funding Readiness & Investigator Capacity Building
- Sessions will focus on grant-writing fundamentals, needs assessment, methodology, budgeting, sustainability, mentor-mentee pairing, and proposal preparation to strengthen investigator-led sickle cell disease research



Key Industry-Sponsored Sessions at FSCDR 2026 (2/3)



- **Agios Pharmaceutical:**

- Focus Areas: Scientific Networking & Poster Engagement
- The reception and poster session will support investigator engagement and visibility around emerging SCD research, with emphasis on community-building rather than a specific asset message



- **Sanofi:**

- Focus Areas: Bridging Polymerization, Inflammation & Innovation in SCD
- The product theater will focus on the relationship between hemoglobin polymerization, inflammatory biology, and emerging innovation pathways in sickle cell disease management



Key Industry-Sponsored Sessions at FSCDR 2026 (3/3)



- **Genetix Biotherapeutics:**

- Focus Areas: LYFGENIA Patient Journey & Gene Therapy Adoption
- The product theater will focus on real patient stories, treatment experience, and practical considerations around the LYFGENIA gene therapy journey in SCD



- **Novo Nordisk:**

- Focus Areas: Proactive Comprehensive Care & Evolving SCD Management
- The product theater will focus on shifting SCD care toward proactive, comprehensive management, supporting Novo Nordisk's broader positioning around long-term disease management



What We're Watching for Post-FSCDR 2026

- Whether etavopivat data across HIBISCUS 2, HIBISCUS Kids, and hemoglobin/end-organ damage analyses will support a broader disease-modification narrative
- Whether osivelotor, voxelotor registry data, and pociredir will rebuild confidence in oral disease-modifying strategies or reinforce caution around safety, durability, and endpoint selection
- Whether Exa-Cel's real-world benchmarking and LYFGENIA patient-journey content will shift gene-therapy competition toward centre readiness, patient navigation, nursing education, and post-treatment monitoring
- Whether CSL's anumigilimab and CSL889 sessions will define a coherent inflammation/VOC development strategy or remain early-stage feasibility signals
- Whether biomarker and endpoint discussions involving Functional Fluidics, FDA, CSL, Agios, and VCU will translate into clearer trial endpoints for pain, hemoglobin, VOCs, and organ damage
- Whether screening and access interventions, including the Gazelle platform, RECIPE linkage coordinators, and community-led stigma reduction, will show enough operational value to influence care pathways beyond academic settings

Strategic Insights and Strategy Development is our focus



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AND INTELLIGENCE



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