ACRO Innovate Advocate Collaborate

CTIS information day

CTIS progress – A CRO perspective

Leona Fitzgerald • 17 June 2026

About ACRO

- Founded in 2001, the Association of Clinical Research Organizations (ACRO) is non-profit trade association representing the world's leading clinical research and technology organizations, which provide specialized services that are integral to the development of drugs, biologics and medical devices that enable patients to live longer, healthier, and more productive lives. ACRO members provide a wide range of specialized services across the entire spectrum of development - from preclinical, proof of concept, and first in human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies employ nearly 470,000 people worldwide and conduct research in more than 90 countries in every global region.

- In 2025 alone, ACRO members conducted or participated in **7,634 studies** involving **1.4 million patients** and volunteers across a wide range of therapeutic areas and geographies that provide drugs, biologics, and medical devices integral to delivering better health outcomes.

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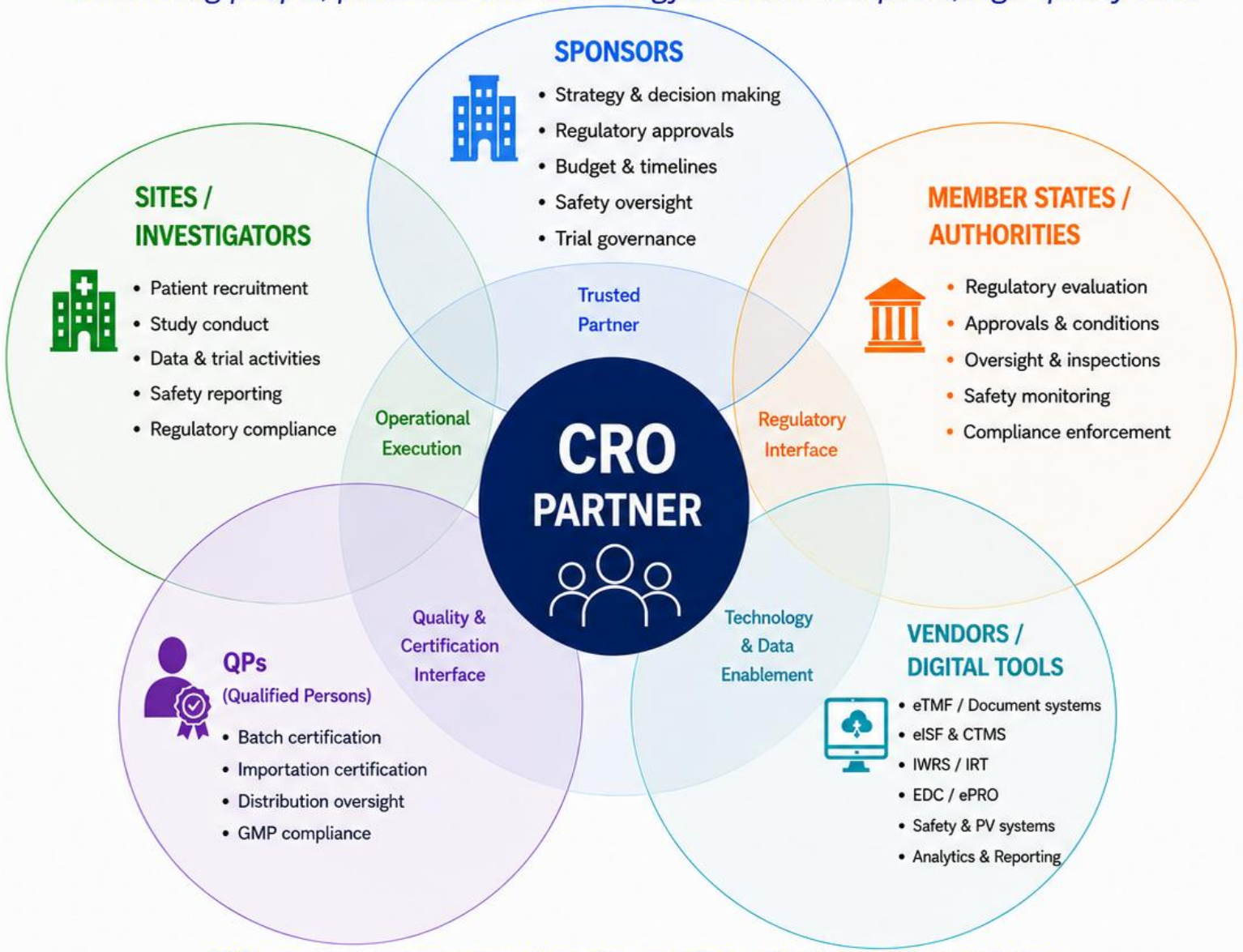
The CRO at the Centre of the Clinical Trial Ecosystem

Connecting people, processes and technology to deliver compliant, high-quality trials



CROs experience many connections. One goal: Safe, effective medicines for patients.

HOW THIS SCALES: MULTIPLE SPONSORS & MULTINATIONAL TRIALS

MULTIPLE SPONSORS

CRO manages diverse therapeutic areas, protocols, and requirements across many sponsors

Many relationships, multiple operating models.

MULTI-NATIONAL TRIALS

Coordinated submissions, country-specific requirements, translations, timelines and approvals

Adaptable planning, many countries.

LARGE SITE NETWORKS

Onboarding, training, monitoring and support for hundreds of sites

Consistent execution at scale.

OPERATIONAL SCALE

Managing hundreds of studies, thousands of study roles, and millions of documents

Scale with quality and efficiency.

SYSTEM & PROCESS INTEGRATION

Integrating digital tools, automating workflows and ensuring data flows across the ecosystem

Connected systems. Smarter trials.

Bringing it all together to accelerate trial delivery, ensure compliance and improve patient outcomes.

Key achievements

System maturity

- Greater platform stability
- Increased user confidence
- Improved usability compared with early implementation
- List of known issues and workarounds

Single EU submission environment

- One coordinated submission process
- Improved visibility of trial status
- Better oversight of multinational trials
- Agreed templates

Operational efficiencies

- Harmonised workflow across Member States
- Improved transparency rules
- Reduced reliance on multiple national systems
- Improved flexibility for non-substantial modifications

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Positive Action

Simplification task force

Improving user management - Roles and Permissions framework

Emails/notices alerts

Parallel substantial modifications where not linked

Industry stakeholder group

Sharing lessons learned – collaborative feedback on new items

Identifying IT issues to surface for discussion

Examples of functionality issues causing application disruption

Faster Timelines

FAST EU – letter of intent process but limited procedure slots

Mono-national study faster timelines

MedEthics EU and CTAG/CTCG collaboration

Best practice sharing

Template agreement

Interim Article 11 workaround

COMBINE pilots

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Challenges

User management – Administrative burden falls to Sponsor admin or CT admins

- Thousands of study roles managed across multiple sponsors
- Continuous onboarding, offboarding and role changes
- No bulk access management capability or download option – Had to develop additional tracking method for view of all roles/permissions
- Users unable to remove their own study roles when responsibilities end

Predictability and Harmonisation

- Variability in Member State implementation remains
- MSs requesting info in different locations in CTIS (e.g. translations, patient materials, financial details)
- Differences in RMS execution create uncertainty
- Additional national requirements reduce efficiency gains from harmonisation

Legal Status Misalignment

- Current study expiry functionality does not always align with recruitment realities
- Projected number of patients to match insurance certificate even though Insurance cover includes overage
- Any substantial modification can effectively reset timelines based on current system experience
- Creates uncertainty regarding long-term study planning
- CROs must continuously forecast recruitment performance and engage sponsors early when extensions may be required
- Data formats not updating to match legislation i.e. PIP number or pick list of product characteristics
- Publication of third party details even after transparency rules changed

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Opportunities

User Management

- Accelerate implementation of the CTIS role simplification framework
- Enable study users to relinquish roles and permissions when their responsibilities conclude, reducing administrative burden and improving access governance.
- Reduce dependency on Sponsor Administrators and CT Administrators for routine access maintenance
- Introduce bulk role management capabilities and enable download options to support large study portfolios
- Improve scalability to meet goals of increasing research in the EU

Lifecycle Management

- Review study authorisation expiry functionality to better align with recruitment realities
- Reduce RFI by not calculating EU patient number predictions as sum of country level numbers per insurance certs
- Enhance visibility of upcoming study expiry milestones
- Support proactive planning for substantial modifications where recruitment forecasts indicate timeline extensions may be required
- Provide portfolio-level reporting to identify studies approaching key lifecycle milestones

Regulatory Innovation

- Consider expanding FAST EU procedure capacity to support broader sponsor participation
- Maintain FAST EU pilot activities until implementation of the Biotech Act framework
- Continue collaborative development through industry stakeholder engagement and feedback forums
- Promote further harmonisation of Member State implementation practices to improve predictability

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