

CIRM Accelerating Center Proposal: ICOC Presentation

June 15, 2016



Objectives of today's presentation

- Alignment between Quintiles and CIRM visions
- Introduction to selected team members
- Value proposition of the proposed Accelerating Center:
 - › Plans to market the center services to attract clients (including CIRM awardees) and highlight the value of the center to accelerate clinical trials
 - › Synergies between the proposed Accelerating Center and CIRM's Alpha Clinics Network and Translating Center
 - › Establishing a sustainable business beyond the 5-year award period
 - › The sum of all value drivers > initial CIRM grant
- Creating momentum for CIRM-Quintiles partnership

Organizational alignment and presenting team



Accelerating stem cell treatments to patients with unmet medical needs



Help our customers make better decisions about drug development, commercialization and drug therapy choices in a manner designed to save them time and money and to deliver better healthcare outcomes for patients



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The Accelerating Center (AC) is fully aligned with Quintiles' vision



Teamwork | Leadership | Customer Focus | Integrity | Quality

Quintiles is well positioned to build and run the AC



Quintiles is focused on enabling the medicines of tomorrow and considers stem cells to be a leading edge technology



The stem cell market is financially attractive and poised for significant growth



Quintiles senior leadership fully supports the AC application



Quintiles has supported stem cell partnerships with other clients



The AC services are already core offerings of Quintiles' Clinical, Strategic Drug Dev't and Advisory Services groups



The AC requires a balance of strategic and operational support and an understanding of the unique needs of emerging biopharma and academic customers

Opportunities exist to improve stem cell therapy development time, cost and probability of success

Limited experience with end to end drug development

- Development of target product profiles
- Integrated drug development planning
- Transition planning
- Analysis of medical and commercial viability
- Indications strategy
- Trial feasibility
- Understanding IND needs

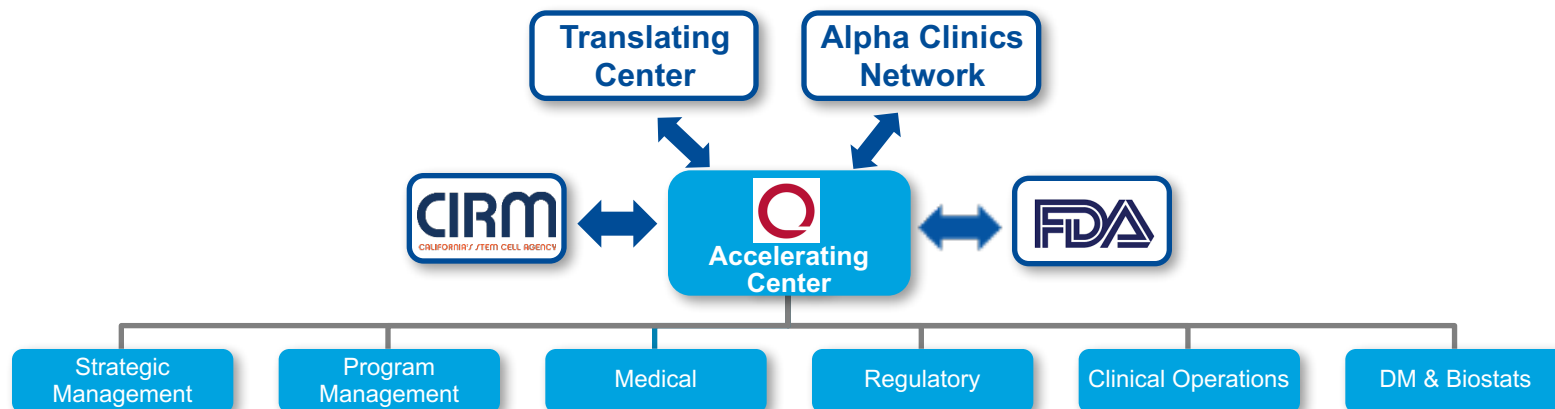
Regulatory path uncertainty

- Proactive regulatory strategy
- Ensuring trial outcomes support registration
- Use of experienced regulatory staff
- Unified voice for the industry to shape the regulatory path

Clinical trial inefficiencies

- Patient centric trial design
- Improving recruitment
- Application of standardized technologies
- Multi-center trials
- Knowledge sharing and best practices
- Adopting learnings from rare disease
- Expand the available sites able to support stem cell trials

The proposed AC will provide end-to-end stem cell clinical development services



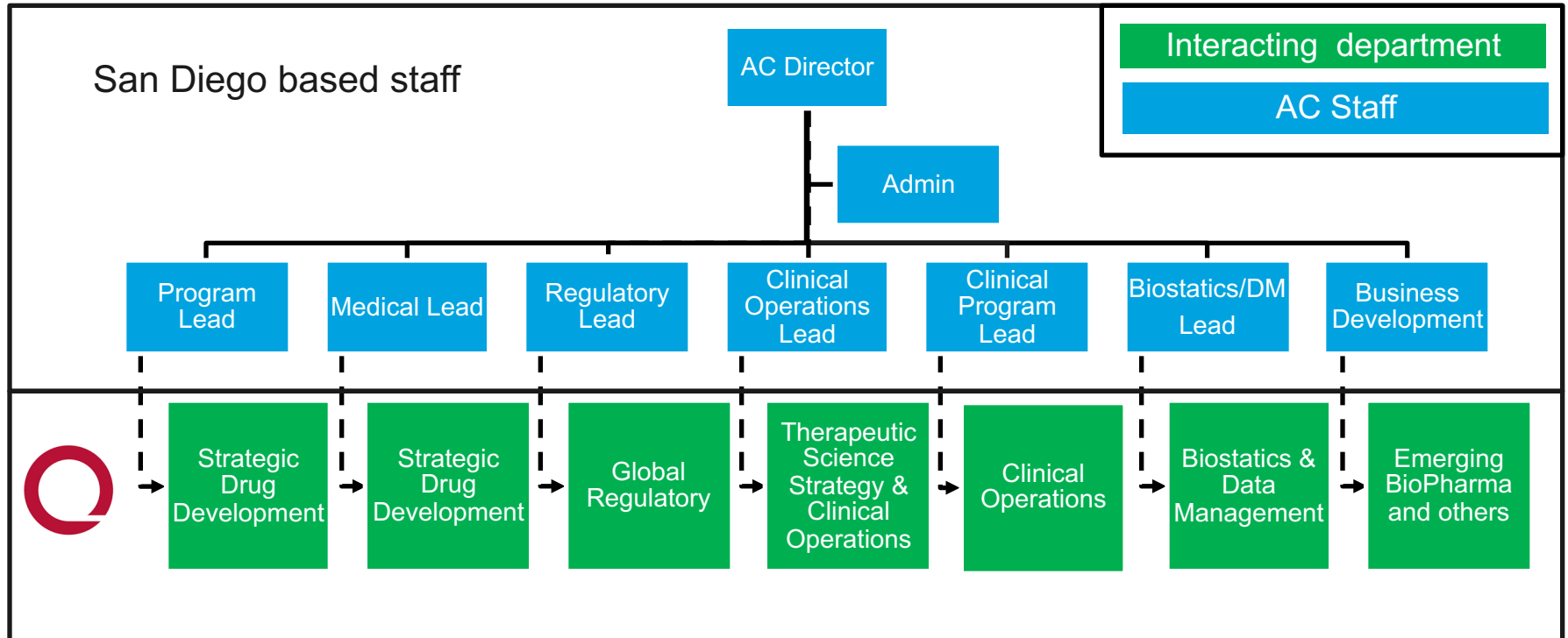
Drug development services and functions

- Coordination with Q, TC, ACN, CIRM
- Center operations
- Governance
- Sustainability
- Integration across activities
- Needs analysis
- Risk assessment
- Standardization
- Contracting
- Client POC
- Clinical strategy
- Development planning
- Biomarkers
- Trial design
- Reg strategy
- Planning
- Agency interactions
- Regulatory documents
- Planning
- Trial design
- Site selection
- Recruitment strategy
- Trial operations
- Site management
- Data management
- Biostatistics
- Analytics
- Interpretation

Business, support and CIRM infrastructure functions

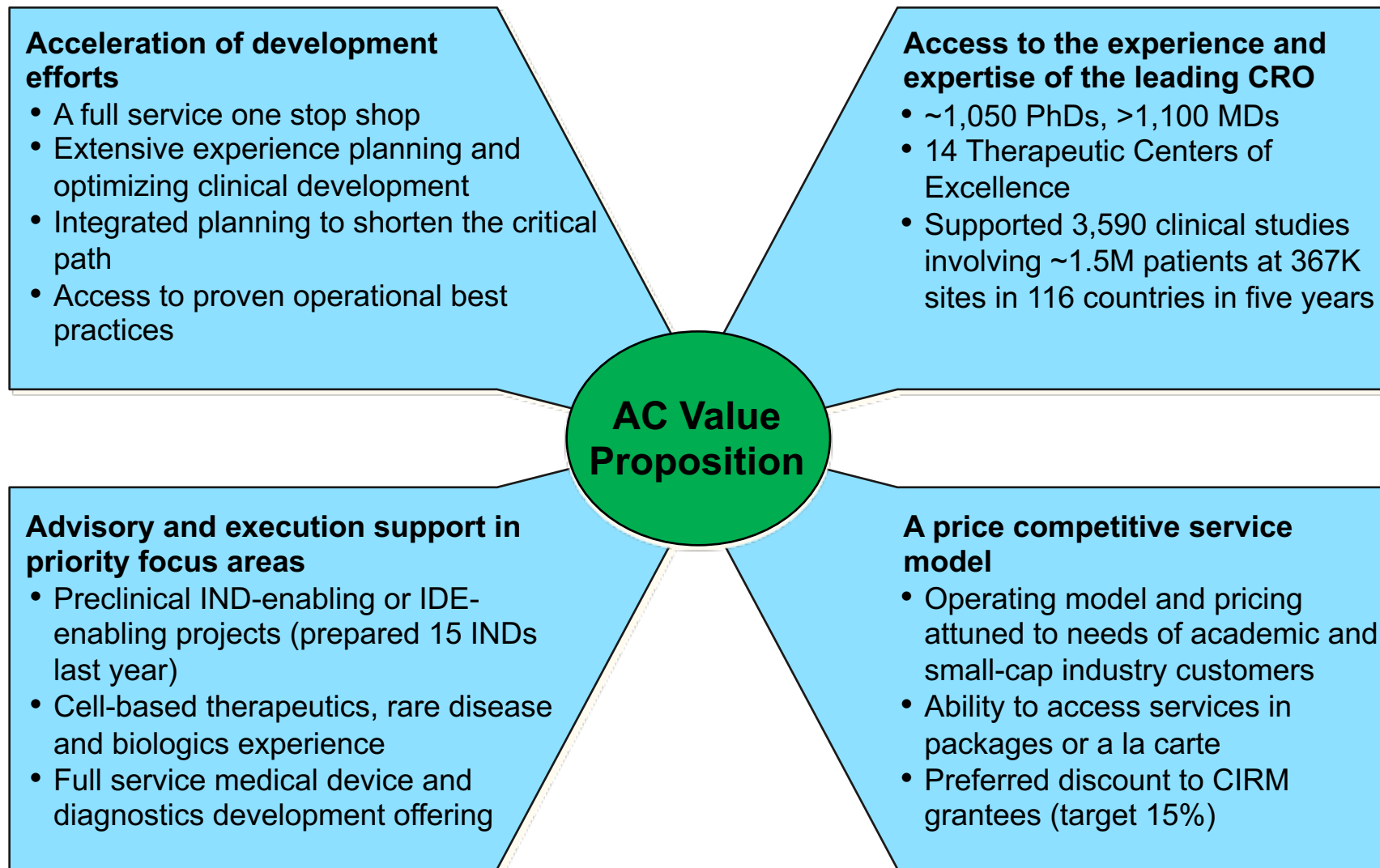
- Business development
- Customer relationship management
- Administration
- Knowledge management
- AVAR strategy and operations
- Clinical operations technology
- CIRM Infrastructure committee
- Communications

The Accelerating Center will have dedicated staff and leverage Quintiles broad functional capabilities



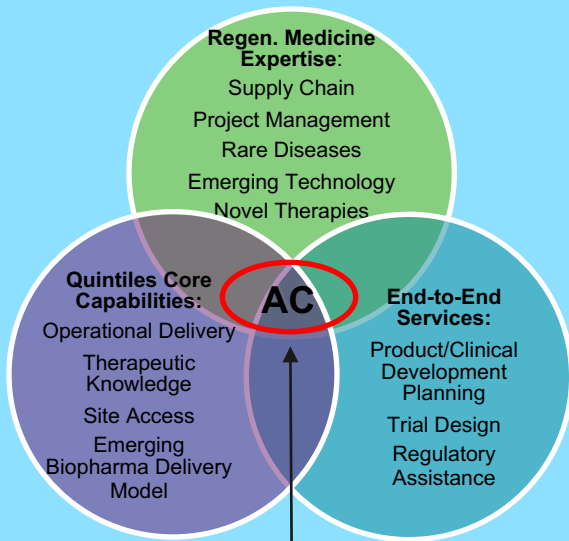
- Actual number of people per position depends on demand
- Operational structure is modeled after similar successful partnerships
- Strategic functions will be led by senior personnel (Snr. Director/VP)
- AC staff partner with other Quintiles departments
 - Seamless integration of strategy and operations
 - The AC roles current exist within these departments
 - Flexible capacity to handle demand fluctuations
 - Personnel development and knowledge sharing within Quintiles

By utilizing Quintiles' scale and expertise, the AC will accelerate clinical development and reduce costs



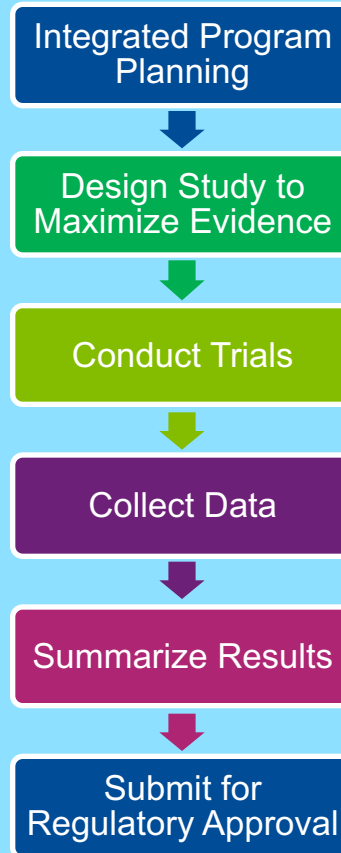
Our model harnesses Quintiles' deep CRO expertise to accelerate stem cell development...

Our core capabilities



The unique level of service that Quintiles can provide

How we will use them



Value to customers

Acceleration of development efforts

Experience and expertise of the world's leading CRO

Strategic and operational support: the right things, the right way, the right time

Price competitive service model

Flexible and customer focused

Targeted AC marketing will leverage the full scale of Quintiles' global business development group

Global scale and reach

Emerging biopharmaceuticals focus

Accelerating Center business development group

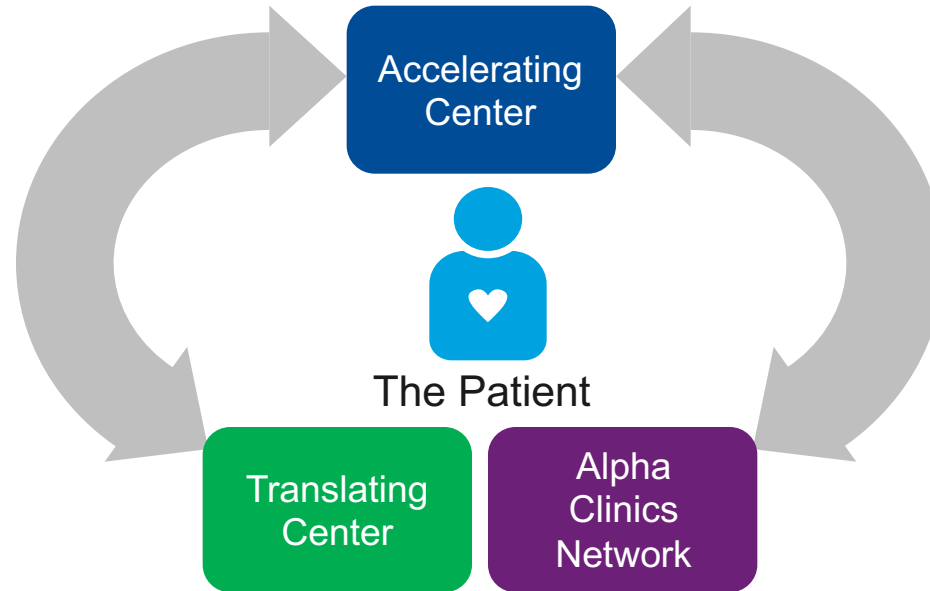


500 trials with 240 emerging biopharma clients in the last 5 years



Relationship Management | Promotional Materials | Conferences | Webinars | Targeting Executives

Synergies between the AC, TC and Alpha Clinics Network will drive acceleration and value



Communications

- Planning & coordination
- Consistency
- Sharing expertise
- Regulatory

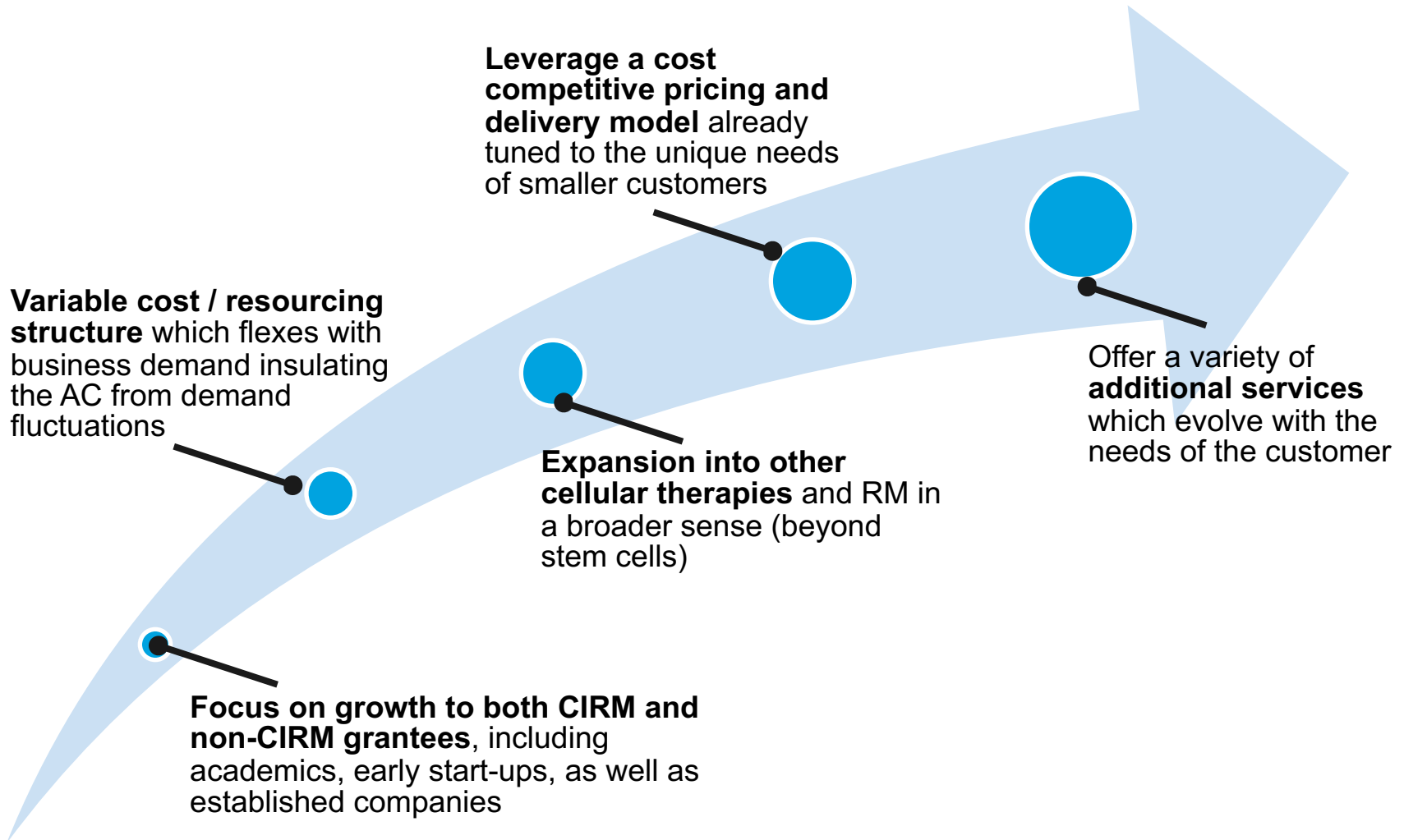
Practice

- Sharing best practices
- Consistent systems
- Recruitment
- Performance tracking
- AVAR development

Business

- Co-marketing
- Sponsor management
- Increased reach and impact

The Accelerating Center will have all the elements to accelerate and sustain long-term stem cell development



Additional services will be added to support the maturing demands of the AC and its clients

Examples of currently offered Quintiles service options to enhance AC sustainability

Taking a product to market

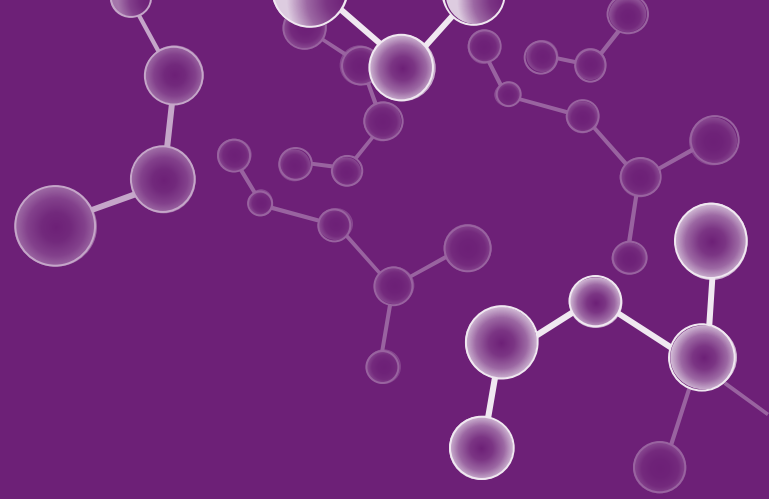
- Indications strategy
- Market access
- Sales strategy
- Health economics and outcomes research (HEOR)
- Phase transition planning
- Real world outcomes

Creating viable commercial entities

- Commercial evaluation and strategy
- Capital strategy
- Exit strategy and planning
- Licensing
 - Due diligence preparation
 - Partner matching

Thank You

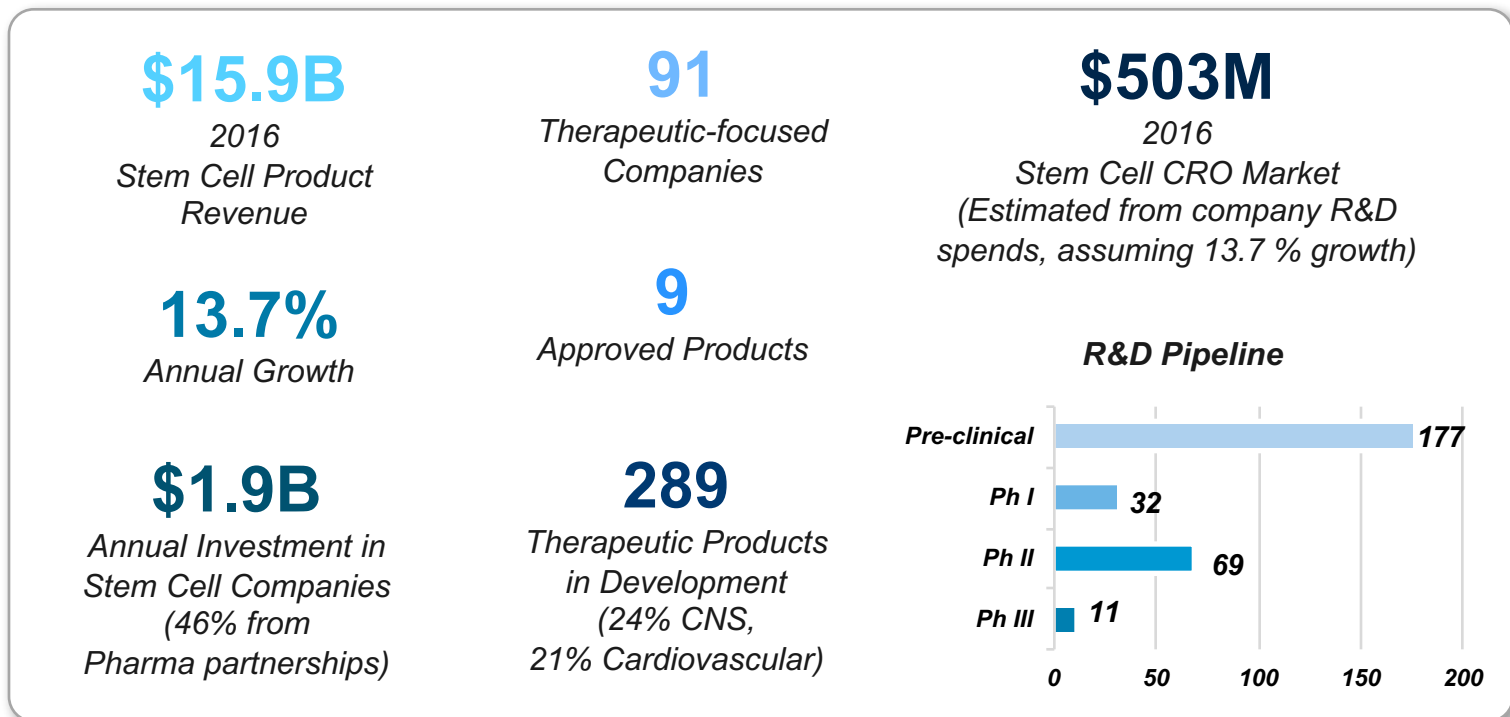
Public Comments / Q&A



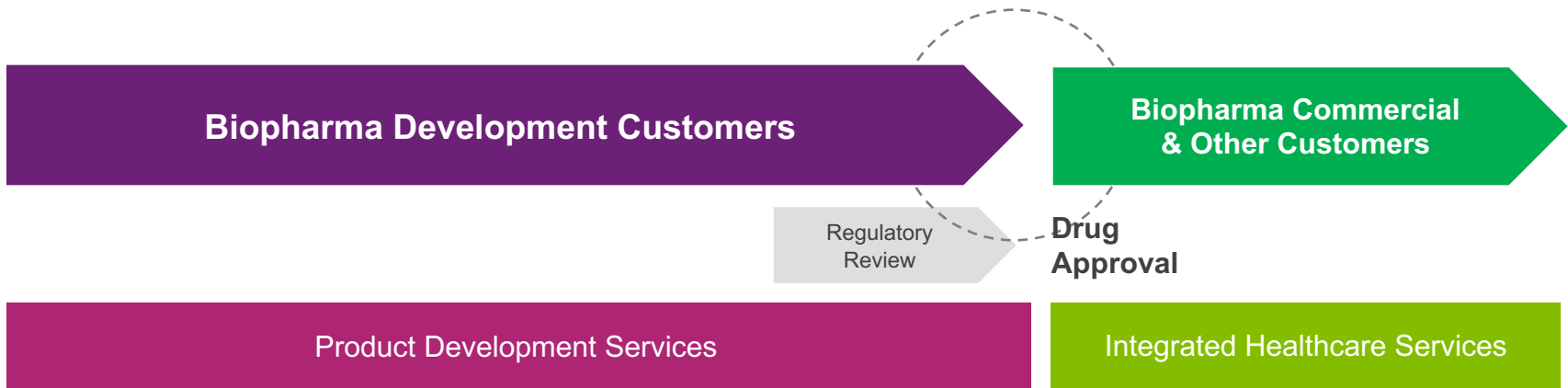
APPENDIX

The stem cell market is actively growing and has a large potential pipeline

- Stem cell therapies account for ~52% of the regenerative medicine market (remainder covers gene therapy, tissue engineering, and biomaterials)
- These therapies use adult, embryonic, or induced pluripotent stem cells to augment, repair, replace, or regenerate organs and tissue, and have potential applications in every disease area
- With a maturing pipeline, it is anticipated that there will be a growing need for stem cell-specific trial expertise and clinical trial services



Quintiles offers end to end drug development services to its customers



Clinical Solutions & Services

Project Management & Clinical Monitoring:

- Study Design & Operational Planning
- Investigator/Site Recruitment
- Site & Regulatory Start Up
- Patient Recruitment
- Clinical Monitoring
- Project Management
- Digital Patient Services

Clinical Trial Support Services:

- Clinical Data Management
- Biostatistical Services
- Central Laboratories
- Bioanalytical Laboratories
- Cardiac Safety & ECG Laboratory Services
- Safety & Pharmacovigilance Operations
- Phase I Clinical Pharmacology Units

Strategic Planning & Design:

- Biomarkers, Genomics & Personalized Medicine
- Model Based Drug Development
- Planning & Design
- Regulatory Affairs Services

Advisory Services

- Product Development Strategy Consulting
- Regulatory & Compliance Consulting
- Process & IT Implementation Consulting

Commercial Services

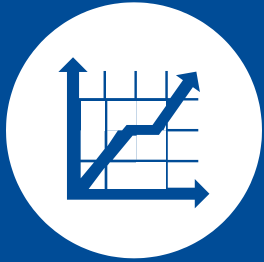
- Contract Sales
- Market Entry / Market Exit
- Integrated Channel Management
- Patient Engagement Services
- Market Access & Commercialization Consulting
- Brand & Scientific Communications
- Medical Education

Outcome/Observational

- Observational Studies
- Product and Disease Registries
- Comparative Effectiveness Studies

Payer/Provider Solutions

Case Study: Stem Cell Clinical Development Alliance



Client Benefits

An efficient operational platform to drive flexible and highly efficient Phase 1-4 clinical development activities for stem cell therapies



Customer Challenge

- A top 5 biopharma was seeking a strategic partner to develop an allogeneic cell therapy for patients with ophthalmic diseases and other assets
- Traditional outsourcing was viewed to possess disadvantages including lack of integration, lack of shared risk, costly duplication and oversight



Our Solution

- Creation of a fully integrated “virtual development” infrastructure which complements the customer’s organization
- Joint governance and management to converge on a optimal operational strategy and approach for clinical execution



Results

- Efficiency/productivity benefits – a dedicated “boiler-room” focused entirely on driving efficiency and productivity gains to facilitate more cost-effective development
- Application of development operations expertise and best-in-class approaches

The AC marketing strategy will complement Quintiles' emerging biopharmaceutical marketing

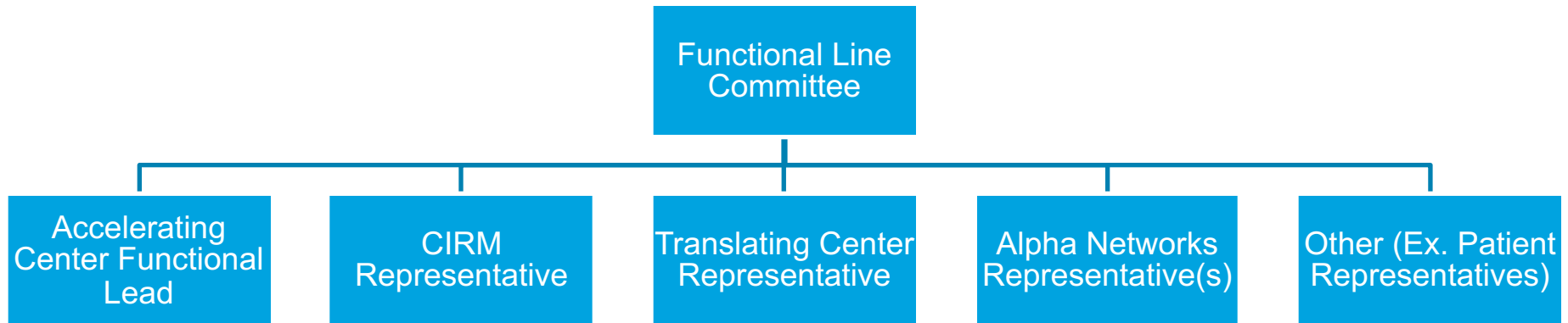
Near Term (Start-up Phase)

- Begin working with Quintiles Emerging BioPharma, Novella, regenerative medicine and rare disease related sales groups within Quintiles
- Hire business development position focused initially on CA customers
- Leverage the marketing power and brand of CIRM and Quintiles
- Contact and meet with CIRM grantees
- Begin working with Alpha Network sites and Quintiles existing sales network to identify leads
- Presence at Stem Cell Meeting on the Mesa (San Diego, Oct 2016)
- Contact stem cell related groups such as the Alliance for Regenerative Medicine
- Public relations releases in scientific and financial media such as Fierce and Xconomy

Long Term (Operate Phase)

- Work with Translating Center to identify leads
- Sponsor meetings
- Symposiums
- Presence at stem cell meetings
- Advertising
- Webinars
- Cultivate relationships with KOLs
- Assist potential CIRM grantees with budget planning
- Establish and leverage relationship with FDA
- Publications and white papers: ex. stem cell clinical development, regulatory environment

AVAR and knowledge sharing communications strategy



Functional line based meetings

- Clinical Operation, Regulatory, Data Management, etc.
- Quarterly meetings
- Sub-group meetings as needed
- Functional line representatives as appropriate
- Goals
 - AVAR development and implementation
 - AVAR needs
 - Knowledge sharing

Opportunity for AVARs and synergies to drive clinical acceleration and improved operations

Accelerating Center & Alpha Clinics Network

- Best practices
- Consistent infrastructure
- Data integration
- Expansion
- Hub and Spoke model
- Multi-site trial
 - Support
 - IRB approval
 - Integration
 - Coordination
- Recruitment
- Site usage optimization
- Sponsor vetting

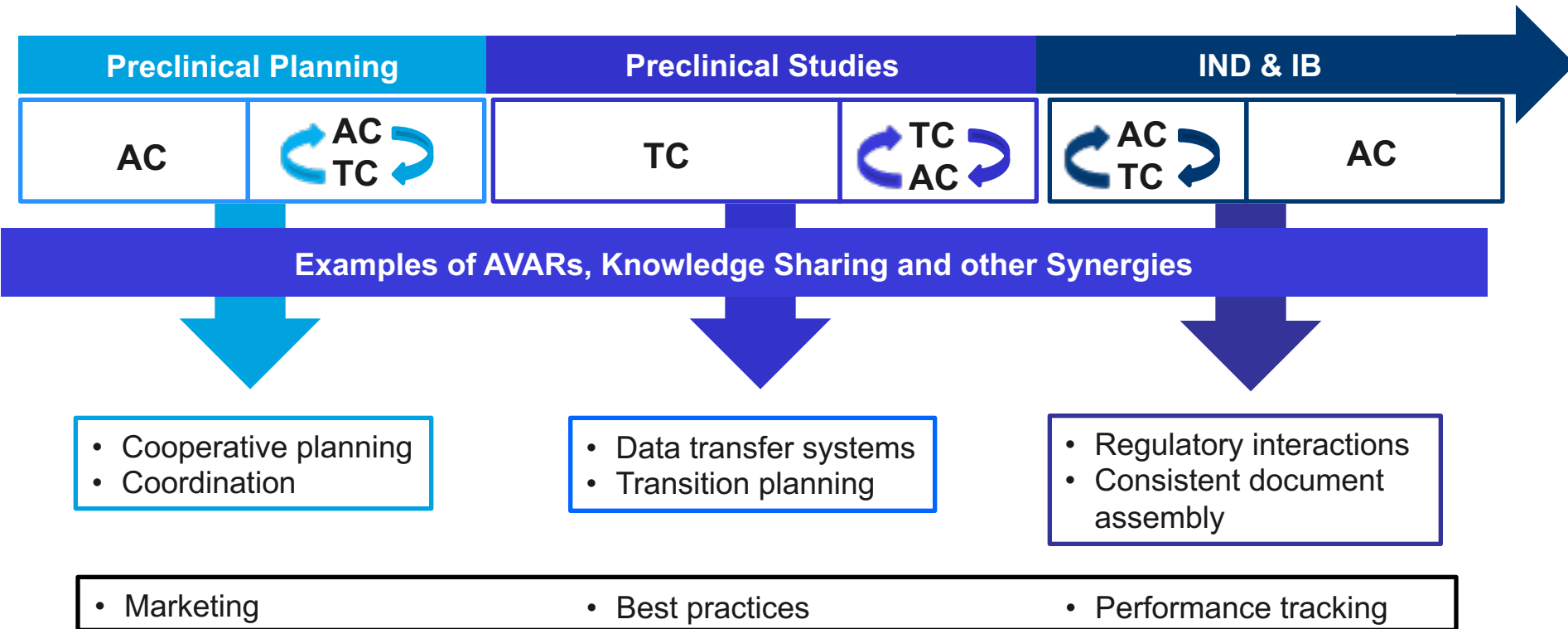
Accelerating Center & Translating Center

- Cooperative planning
- Consistent and repeated regulatory interactions
- Data transfer systems
- IND assembly and submission systems

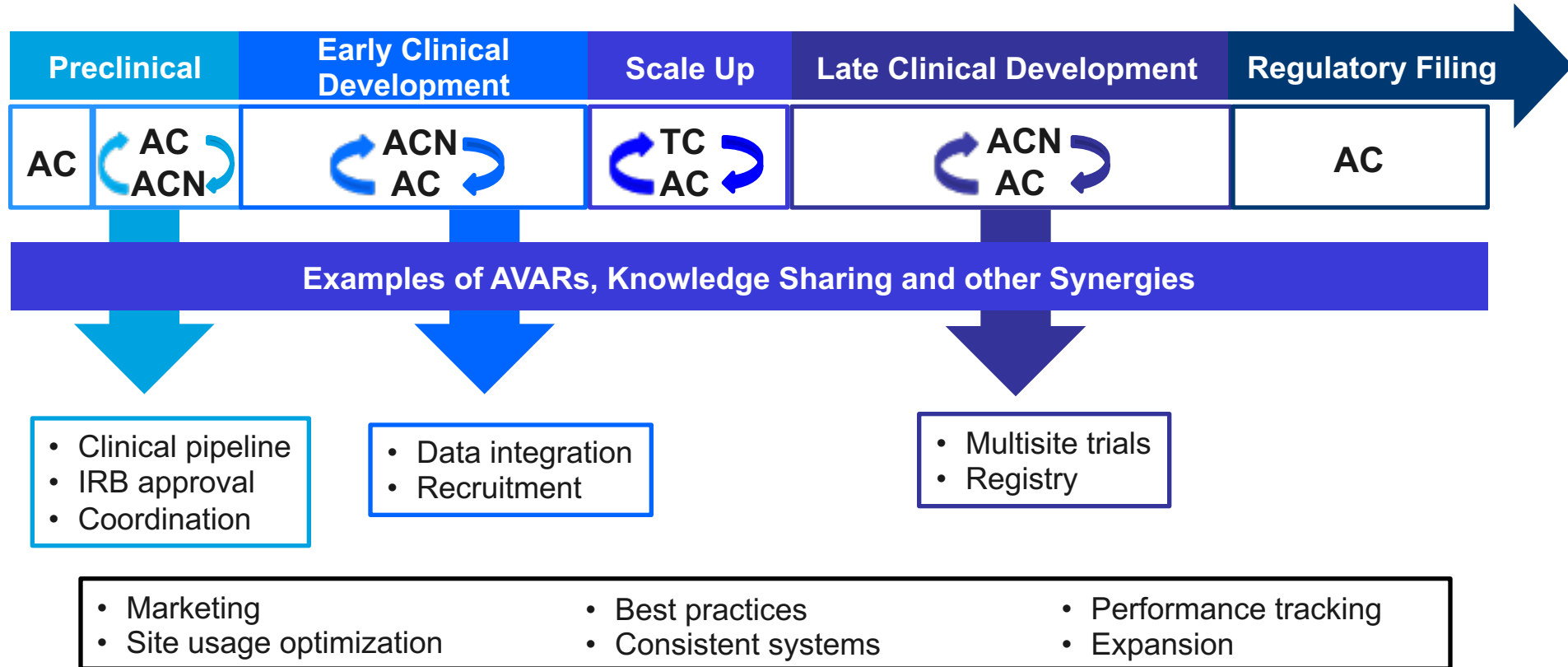
All CIRM Infrastructure Groups

- Cooperative strategy
- Communications
- Data sharing
- Integrated planning
- Marketing
- Performance tracking
- Transition planning
- Cooperative feedback and influence on regulators

There are synergies at every point of AC and TC interaction



There are synergies at every point of AC and ACN interaction



The AC will lead the process to develop, evaluate, and implement AVARs

