2025 UPDATE ON POTENTIAL DEVICES, DIAGNOSTICS, & THERAPEUTICS

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The Rady-OC Virtual Incubator

Research Strategic Plan for acceleration of peds devices

- WHAT? Calls for us to build out a peds device incubator or accelerator
- WHY?
  - Ethical responsibility to promote peds devices
  - Promote RADY as a top destination for peds medical device testing and innovative research on devices
  - Leverage our geographic locale in center of MedTech ecosphere
  - Generate an economic engine for RADY and for OC/San Diego Counties by accelerating devices

HOW? Current approach:

- Utilize Nadine Afari to source promising devices
- Develop early phase partnerships-pre FDA clearance/approval
- Partner with Octane and City of Irvine to provide full service acceleration
- Build capacity towards becoming a MPDTCU
- Use "wins" to apply for SHIP hospital status

The Rady-OC Virtual Incubator

Test cohort June 2025-June 2026

- Opportunity to try our incubation skills for a few devices
- Leverage our unique position and resources to support early stage devices
- Demonstrate CHOC is a key local partner for OC founders and others
- Apply for grants, attempt device trials and other efforts to test our limits and highlight areas for improvement
- Align infrastructure, assess needs for future growth of incubator
- Develop a strategic direction and phase growth

Update December 2025 –Lessons Learned

- No clear legal pathway for partnership
- No dedicated fast-lane for ARC review of experimental devices regardless of risk
- Strategic direction for the incubator not aligned with RI processes and infrastructure
- RI Leadership focused on managing operations for merger, growing budget and FTE, fitting device trials into normal research operations, and improving basic research operations
  - No prioritization of device partnerships in research
  - No defined processes for effective management of projects, research requests, and founder's needs (all ad hoc via email requests using extant personnel)
  - Limited expertise and experience among regulatory staff or managers for devices
- Future opportunities will require us to align strategic direction to new processes and a develop a plan to stage growth

The 2025 Cohort of Companies

Leasing space:

Omaroon: https://www.omaroon.com/

Interro IQ, Inc. https://www.interroiq.io

Syntr Health Technologies, Inc.: https://syntrhealth.com/

Implementation/clinical trial:

Canva Dx: https://cognoa.com/

Industry Education/partner:

Innopiphany: https://innopiphany.com/

In process/planned partnering with PIs for CHOC RI:

Syntr Health Technologies, Inc.: https://syntrhealth.com/

Epinex: https://www.epinex.com/

KiHealth: https://www.kihealth.com/?srsltid=AfmBOooaMDJcOqmOBVRU20yVD4KVr17yKCr1xMLzpRwmlMJvUDyhhh

CoreDX: https://cordx.com/

Centralive: https://centralive.health/

Sanofi: https://www.sanofi.com/en/patients/understanding-diseases-conditions/diabetes/autoimmune-type-one-diabetes

Other

Ventris medical

AcQumen

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2026 Update on Biostats Innovation Collabs

- **Cardiology**
  - Digital twinning-tool to develop “counterfactual examples” to test hypotheses
  - Virtual Pectus patient -Simulation of complex cardio-pulmonary and chest wall dynamics- (Dr. Renella, Dr. Kabeer, University of Genoa)
  - Digital twinning-Fontan patient optimizing surgical intervention (Dr. Starr, Dr. Kelly).

- **Device testing**
  - Promoting *in silico* evidence testing for SaMD
  - Ventris medical –data analytics for device testing
- **GI**
  - Remote monitoring (Dr. Chogle and UCI); agentic component
- **Population Health**
  - RSV #1-Query-based agent to provide analytic insights based on Clauda and RSV data to identify RSV vaccine “hot spots” in OC (dr. Winkler)
  - RSV #2- Applying game theory to improve forecast of vaccine geo-dynamics (dr. Winkler)
  - *TOAST-Targeting Obesity in AdoleScents with Obesity* prototype agentic health coach. (Dr. Weiss, Dr. Casilang, Centralive)
  - Food as Medicine-content added to health coach

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2026 Proposed Process for Incubator Growth

- Create a process to review opportunities monthly or quarterly
- Create a Rady incubator stakeholder's group
  - Key research personnel
  - Clinical and other stakeholders
  - Experienced PIs with skills and interest in MedTech
- Develop clear incubator goals and tasks
  - Assess organizational readiness to incubate
    - Resources
    - Training
    - Data
    - Regulatory
  - Develop a plan to implement incubator goals
    - Grow capacity
    - Target key partnerships
  - Develop incubator criteria
  - Identify incubator partners
  - Implement and assess incubator criteria

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2026 Organizational Readiness

- Infrastructure
  - Formal independent Intake system, vetting, communications, referrals
  - Coordination with pipelines
  - Tracking system
  - Transparency in deliverables, costs
  - Strict timeframes for deliverables
  - Easy data access for exploration, recruitment, and trial optimization
  - Trial management system with embedded costs
- Resources
  - Permanently assigned portfolio project director/manager and assistants
  - Independent budget with funding
  - Available dedicated “Hubs” or PIs
  - Scientists, engineers, device founders and investors
  - Legal support specifically for contracting
  - SBIR dedicated support; Trial support
  - FDA support
- Other Needs/Training
  - Regulatory experience
  - Device recruiting
  - Specific lane in Foundation for peds device gifts to “de-risk” investment
  - Financial and other incentives for clinicians
- Clear Criteria
  - Impact/novelty
  - Commercial viability
  - Shared success
  - Patient/population fit
  - Resources required
  - Clinical fit and capabilities
- Planned Growth
  - Leadership
  - Strategic planning
  - Funding
  - Additional resources

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Appendix A : Details for 2026 Proposed CHOC/Rady Incubator Selection Criteria

- **Impact Assessment**
  - **Outcomes improvement**: Degree of clinical benefit expected for patients/families
  - **Standard of Care Improvement**: Measurable advantages over current approaches (outcomes, safety, workflow)
  - **Workflow Efficiency Gains**: Time and resource savings for clinical teams
  - **Cost-Benefit Profile**: Economic advantages for healthcare delivery
  - **Quality of Life Enhancement/Reduce Burden of Care**: Patient experience and functional improvement potential
  - **Scalability Beyond CHOC/Rady**: Applicability to Broader Pediatric Healthcare Environments
  - **Health Equity Advancement**: Potential to address disparities in care or outcomes
  - **Transformative Potential**: Capacity to fundamentally change practice paradigms in pediatric care

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2026 Proposed Selection Criteria cont'd

- **Patient Availability, Population Exploration, Trial Design, and Data Access**
  - **Target Population Presence**: Sufficient numbers of relevant patient population at CHOC
  - **Data Access to RWE, Exploration and Sample Optimization-**Capabilities **to** optimize trial design and sampling
  - **Patient Recruitment Potential**: Established pathways to identify and engage appropriate patients
  - **Demographic Representation**: Availability of diverse patient populations reflective of target markets
  - **Follow-up Capabilities**: Infrastructure for patient tracking and long-term outcomes assessment
  - **Ethical Considerations**: Clear pathway for appropriate consent and patient safety protections
  - **Competitive Study Landscape**: Assessment of other ongoing studies that might compete for the same patients

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2026 Proposed Selection Criteria cont'd

- **Resource Availability**
  - **Technical Infrastructure Readiness**: Necessary systems, equipment, and IT support
  - **Staff Expertise Alignment**: Availability of personnel with relevant skills and knowledge
  - **Time Commitment Feasibility**: Realistic assessment of clinician and staff time requirements
  - **Departmental Support**: Buy-in from relevant clinical and administrative departments
  - **Physical Space Availability**: Appropriate facilities for implementation and evaluation
  - **Financial Resource Allocation**: Budget alignment with project requirements
  - **Cross-Functional Collaboration**: Mechanisms for interdisciplinary teamwork and communication

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2026 Proposed Selection Criteria cont'd

- **Clinical Capabilities and Fit**
  - **Clinical Problem Definition**: Clarity and precision in defining the clinical need being addressed
  - **Clinical Champion**: Presence and commitment of CHOC clinical advocates
  - **Clinical Evidence Needs**: (conceptual, preliminary data, pilot studies, IRB clinical trials)
  - **Clinical Implementation Feasibility**: Ease of integration into clinical workflows and systems
  - **Regulatory Pathway**: Knowledge and ability to meet FDA/regulatory requirements
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2026 Proposed Selection Criteria cont'd

- **Shared Success Model/Partnership**
  - **Stakeholder Value Alignment:** Families, providers, patients, payers, health system
  - **Revenue Sharing Framework**: Transparent mechanisms for distributing potential income
  - **Brand Association Parameters**: Guidelines for CHOC name and reputation utilization
  - **"De-Risking" Assessment-:**Fair allocation of financial upside relative to contributions
  - **Intellectual Property Rights**: Clear ownership and licensing arrangements
  - **Publication and Recognition Rights**: Academic credit and authorship guidelines
  - **Follow-on Innovation Rights**: Process for managing subsequent improvements and applications

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2026 Proposed Selection Criteria cont'd

- **Commercial Viability**
  - **Reimbursement Pathway:** Payment Mechanisms
  - **Exit or Commercialization Strategy**: An agreed approach for technology transfer or spinout
  - **Timeline Feasibility:** Realistic timeframes for clinical trials, testing, or evidence generation
  - **Adoption Barriers:** Understanding of challenges to purchasing, implementing
  - **Competitive advantage: I**dentifiable differences from alternatives
  - **Sustainable Revenue Generation:** Growth and robust revenue strategy

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Questions? Comments?