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CTRI 2.0

Facilitating and improving research




Clinical and Translational Research Institute [CTRI]

Funded by: UCSD institutional funds, CTSA, UCOP, industry and NHLBI U54

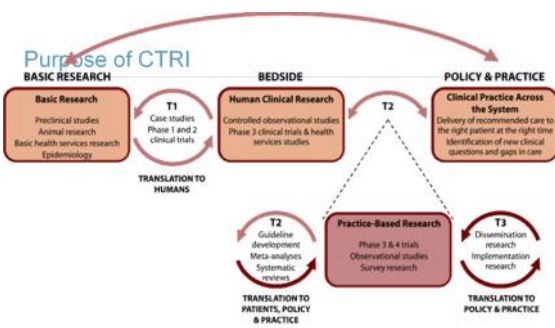
- CTSA: \$37.2 M (2010-2015); \$52 M (2015-2020)
- CTRI Supports:
 - Informatics and biostatistics
 - Clinical research infrastructure
 - Pilot project grants
 - KL2/TL1/CREST programs

>1000 members

- 900 UCSD
- SDSU, Sanford Burnham, Salk, LIAI, Venter, others




Purpose of CTRI

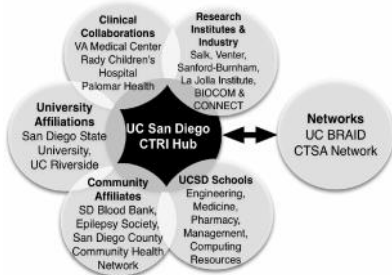


The diagram illustrates the flow of research from basic science to clinical practice. It is divided into three main stages: **BASIC RESEARCH**, **BEDSIDE**, and **POLICY & PRACTICE**. **BASIC RESEARCH** includes preclinical studies, animal research, and epidemiology. **BEDSIDE** includes human clinical research with phase 1 and 2 trials, controlled observational studies, and health services studies. **POLICY & PRACTICE** includes clinical practice across the system, delivery of recommended care, and identification of new clinical questions. Transitions are marked as T1 (Basic to Bedside), T2 (Bedside to Practice-Based), and T3 (Practice-Based to Policy & Practice). Practice-Based Research includes phase 3 & 4 trials, observational studies, and survey research. Translations are noted as 'TRANSLATION TO HUMANS' (Basic to Bedside), 'TRANSLATION TO PATIENTS, POLICY & PRACTICE' (Practice-Based to Bedside), and 'TRANSLATION TO POLICY & PRACTICE' (Practice-Based to Policy & Practice).

To develop innovative solutions that will improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public



Clinical & Translational Research Institute



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Altman CTRI Building



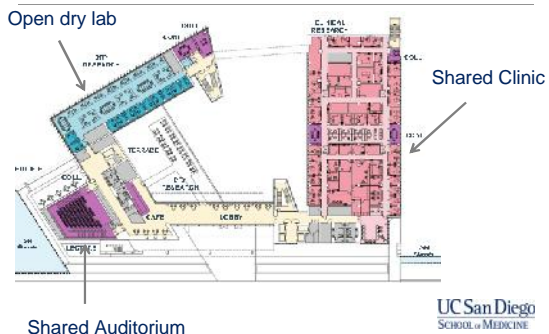
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Altman CTRI Building



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Altman CTRI — shared clinical & research space



Community Engagement Unit, CTRI

2010 to 2015:

Focus: Resources that explain research to the community

Developed:

- Research-relevant Training for CHW/Promotoras – <http://ctri.ucsd.edu/community/Pages/Community-BasedOrganizations.aspx>
- High school: Interactive class (research principles: purpose of research, control group, randomization, informed consent, etc).
- Courses in Community Engagement (targeting Researchers to learn about community) <http://ctri.ucsd.edu/education/Pages/CoursesCE.aspx>
- ResearchMatch.org <http://ctri.ucsd.edu/clinical/Pages/using-ResearchMatch.aspx>



Community Engagement Unit; Videos that Explain Research (example: what is randomization)



Community Engagement Unit, CTRI

2010 to 2015:

Developed bilingual videos

• **Videos that explain research:**

- **What is random assignment?**
- **What is a control group?**
- **Who can participate in research?**
- **How is research made safe?**

www.youtube.com/user/HealthResearchUCSD



Community Engagement Unit, CTRI

2010 to 2015:

Focus: develop resources that explain research to the community

- **Posters promoting research participation –**
(note: Spanish posters are not yet shown on this page. But we have some)
- <http://ctri.ucsd.edu/community/Pages/HealthCareProviders.aspx>

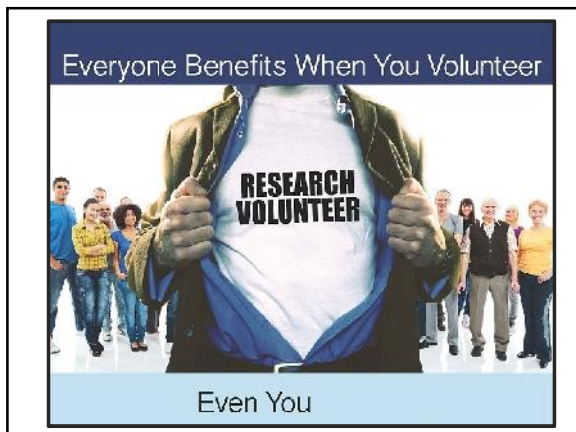


Each One of Us Holds a Piece of the Research Puzzle.

Help us solve it.

Consider
Joining







Community Engagement Unit, CTRI

2016-2020

Change of Focus for CTRI (although not for CTSA/NIH):

- **Get community input into academic research**
- Improve recruitment/accrual efficiency**
- Dissemination and implementation research

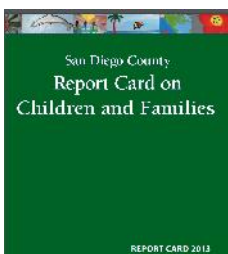
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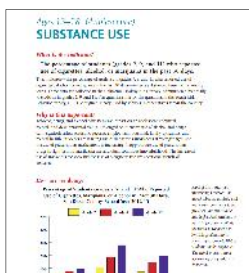
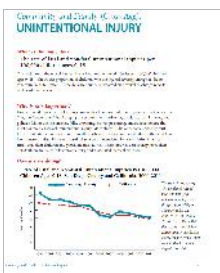
Community input into academic research

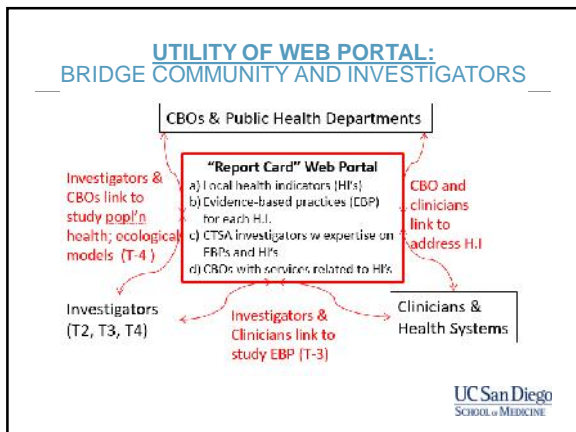
1. Community members review all CTRI-funded pilot awards, (even complex early stage science), and will review many awards for community relevance.
2. Community Advisory Board
3. Web Portal for local health indicators*
4. Community input into large health record data base analyses



More on the web-portal







Community Engagement Unit, CTRI

2016-2020

Change of Focus:

- Get community input into academic research
- **Improve recruitment/accrual efficiency****
- Dissemination and implementation research

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Participant Recruitment Resources [with Bioinformatics]

Current Resources to be improved

- a. Research Match
- b. UC ReX
- c. Data concierge [identify
- d. pSCANNER
- e. Introduction of Investigators to community agencies

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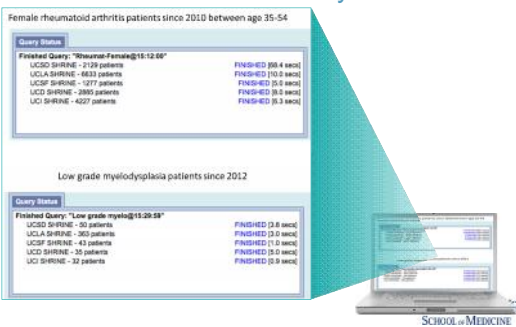
UC Research eXchange (ReX)

Federated Clinical Data Repository

- Funded by UCOP
- 13.5M medical records
- Cohort discovery
- Quality improvement and research



UC Research eXchange (ReX): Cohort feasibility



Participant Recruitment Resources [with bioinformatics unit]

Planned Resources

- Mobile Blood Units distant from UCSD as research clinics
- Eisenhower Medical Center
- "MyChart" for research patient preferences
- FACTS (Find the Appropriate Clinical Trial)
- NIH-NCATS: "Recruitment Innovation Centers"



Community Engagement Unit, CTRI

2016-2020

Change of Focus:

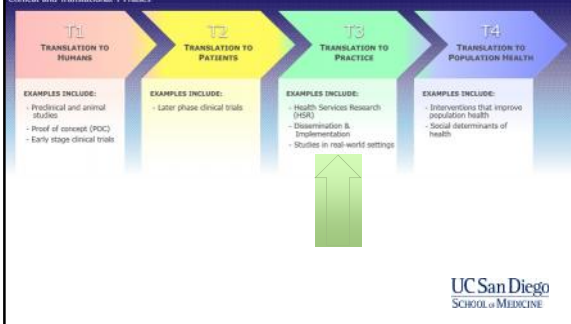
- Get community input into academic research
- Improve recruitment/accrual efficiency
- **Dissemination and implementation research**



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CTRI: Dissemination and Implementation Research

Clinical and Translational T Phases



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CTRI: Dissemination and Implementation Research

1. Pilot funding specific to dissemination and implementation research;
 - \$60K per year, (each grant ~ \$15K to \$30K)
 - prioritize new research / researchers that would not have engaged in T3 research
2. Increase capacity of investigators to conduct implementation science
 - consultation to investigators
 - encourage participation in existing seminars/courses
 - provide scholarships to national courses
 - technical assistance for applications to national courses
 - ? UCSD host one annual UC- implementation science symposium

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Other pilot project grants

- Focus on junior investigators
- \$15-50 K per 1year grant
- Traditional categories
 - Clinical and Translational research
 - Innovative technology
 - Galvanizing Engineering in Medicine (GEM)
 - Pilot Academic—Community partnership research
- New categories
 - Lifespan research
 - Clinical research processes
 - Science of Team Science
 - Dissemination and Implementation Science



More CTRI resources to facilitate research

CTRI resources to facilitate research

- Administrative support to develop and launch clinical studies
 - Rapid Research Trial Teams (R2T2)
 - Clinical Trial Project Organization (CTPO) teams
 - Workflow, Outcomes and Quality Improvement Office (WOQI)
- CTRI Center for Clinical Research
 - Project Manager Service
 - Clinical research space
 - Infusion center
 - Sample acquisition
 - Clinical cores (exercise, echo, DEXA, skin biopsy)
 - Phase I unit
 - Nurses, coordinators, phlebotomy
 - Experimental pharmacy

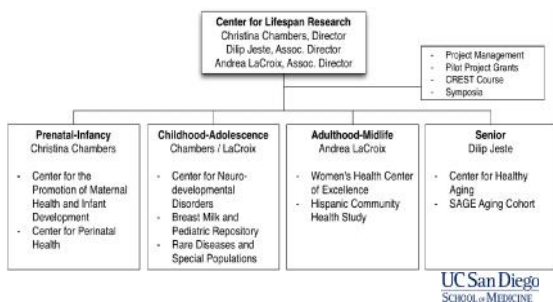


Clinical and Translational Research Institute

- Clinical services since 2011, including:
 - 148 protocols currently active in CCR
 - ~ 3000 visits/year
 - 238 infusions since 2013 (179 in 2014)
 - 418 skin biopsies since 2012 (36 in 2014)
 - 72 IRB submission consultations since 2012
 - 90 consults to facilitate recruitment and enhance diversity



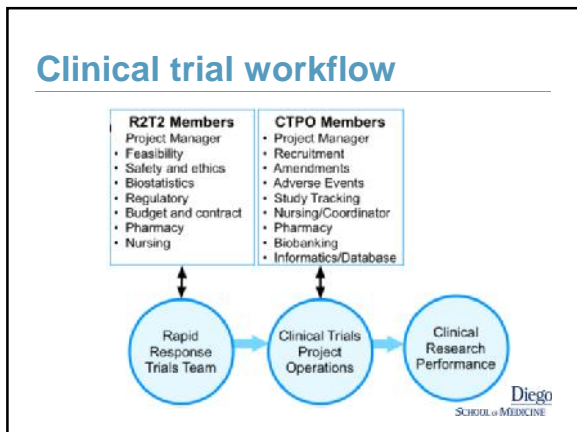
CTRI coordinates specialized research centers

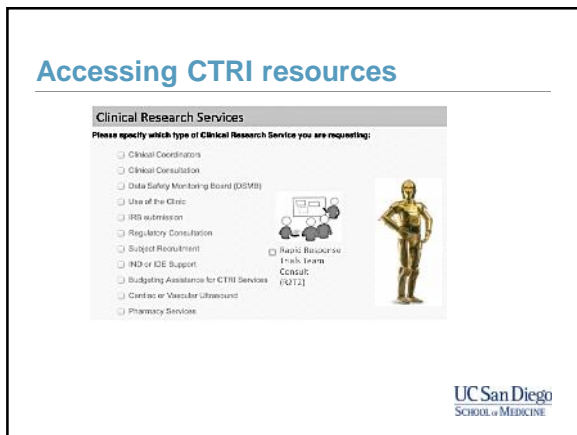


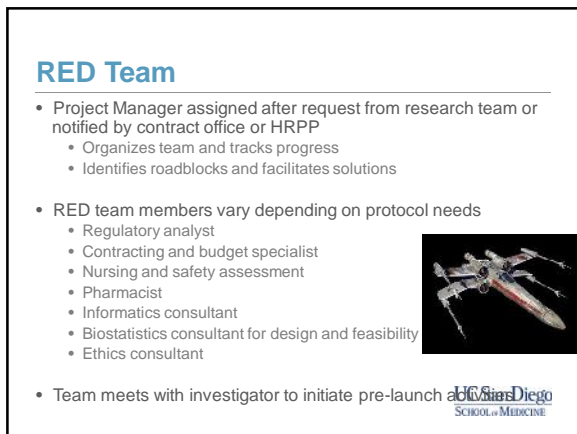
Project Manager Service

- Review, triage and track service requests
- Coordinate and manage pre-launch (RED team) and post-launch activities (CTPO)
- Develop timelines and track milestones
- Manage regulatory and administrative hurdles
- Track enrollment and institute action plan if needed
- Assure high quality and timely data collection

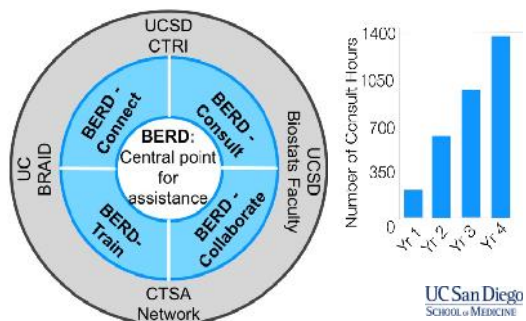








CTRI biostatistics support



Performing studies: Clinical Trial Operations Teams (CTPO)

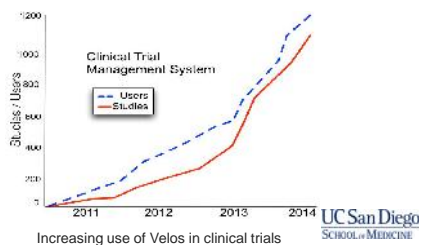
- Project manager transitions project from R2T2 to Clinical Trial Project Operations (CTPO)
 - Assembles CTPO team members and resources
- CTPO manages Center for Clinical Research (CCR) resources
 - Space
 - Coordinators/Nurses
 - Infusions
 - Experimental pharmacy
 - Phlebotomy
 - Sample collection and processing
 - Informatics assistance
 - Biorepository services
 - Biomarker services



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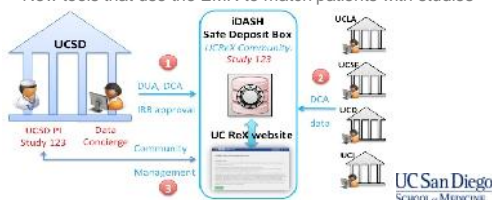
CTRI informatics tools for clinical research

- Velos
- REDCap
- iDASH and HIPAA-compliant data storage



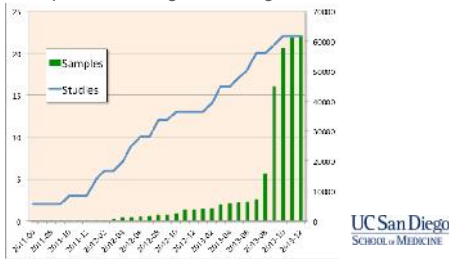
Tools for clinical trial accrual

- Study feasibility and participant recruitment services
 - UC ReX
 - ResearchMatch
 - Data concierge
- New tools that use the EMR to match patients with studies



CTRI biorepository support

- Sample processing
- Biorepository services
- Velos eSample for tracking and linking to the EHR



CTRI: beyond San Diego; a collaborative hub

- UC BRAID
- “Engage UC” for Biorepository consents
- NCATS Accrual to Clinical Trials
- NCATS IRB Reliance
- NCATS Good Clinical Practice project
- NCATS Scientific Review project

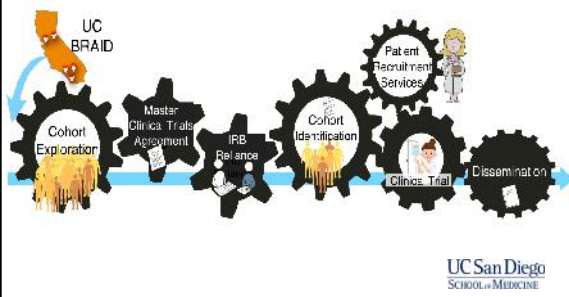


CTRI as a collaborative hub: UC BRAID

- Created in 2010
- Shared Vision: to integrate resources and talent across UC to accelerate research that improves health



BRAID and improved clinical trial efficiency



UC BRAID and improved Breast IRB efficiency

- IRB reliance agreement between UCs
- 39 studies with duplicate IRB reviews across UC

UC TrialQuest

search 3,059 studies from 5 UC health campuses

UCSD UC UCLA UCSD UCSF active pending inactive

Campus & ID	Status	Study Title	Clinical- Trial.gov ID
UCSF #12-10075	active	CCR 12407: A Randomized, Open-Label, Phase 2 Study of the IDO Inhibitor INCB04360 versus Tamoxifen for Subjects with Biochemical-Recurrent Only Epithelial Ovarian Cancer, Primary Peritoneal Carcinoma	01681233
UCSD	active	INCB04360: A Randomized, Open-Label, Phase 2 Study of the IDO Inhibitor INCB04360 versus Tamoxifen for Subjects with Biochemical-Recurrent Only Epithelial Ovarian Cancer, Primary Peritoneal Carcinoma or Fallopian Tube Cancer Following Complete Remission with First-	
UCLA #12-00002	active	Tamoxifen , Low-dose Tamoxifen for Radiation-Induced Breast Cancer Risk Reduction: A Phase Ib Randomized Placebo-Controlled Trial	01794935

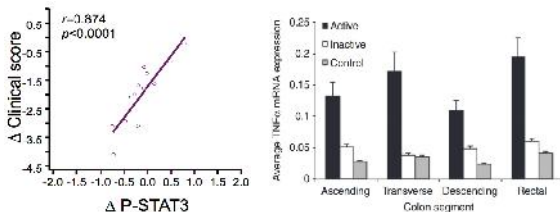
Center for Accelerating Drug Development

- Multi-disciplinary early proof-of-concept clinical trials
- Improve drug safety, efficacy and dosing assessments
- De-risk trials with clinical endpoints
- Novel study designs, eg, n of 1 studies
- Key elements
 - Phase I Unit
 - Biomarker Laboratory
 - Center for Computational Biology



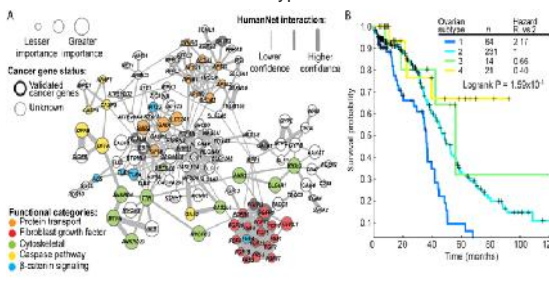
CADD: CTRI biomarker laboratory

Biomarker studies in RA and IBD

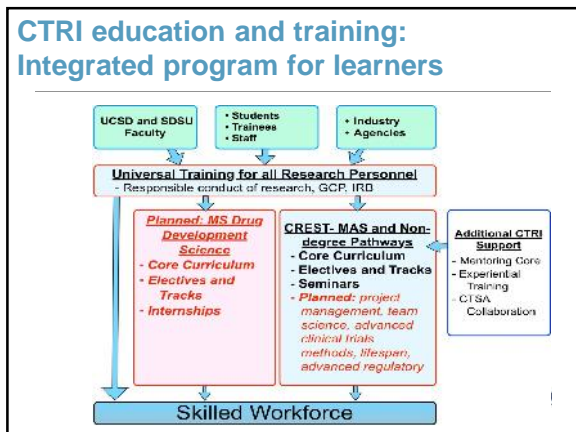


CADD: Center for Computational Biology

Network-based stratification of somatic tumor mutations:
Survival in ovarian cancer subtypes



CTRI education and training: Integrated program for learners



CTRI education and training—CREST

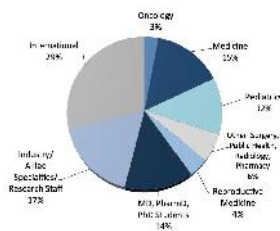
404 enrollees since 2010

Core curriculum includes:

- Biostatistics
- Epidemiology
- Patient-oriented research
- Bioinformatics
- Health services research

Master of Advanced Studies Degree with additional coursework and practicum

Future CTRI plans:
Master of Drug Development Science Degree



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CTRI Mentored Career Development Program (KL2)

- 2-3 years funding for research, instruction, career mentorship training
- Leads to individual K or R award
- 14 awarded since 2010
- 80-90% receive significant funding within 2 years
- New areas of emphasis:
 - Increased number of scholars from 3 to 8
 - Improved diversity
 - New courses (Masters in Drug Development Science)
 - Mentoring Core
 - Mini-sabbaticals

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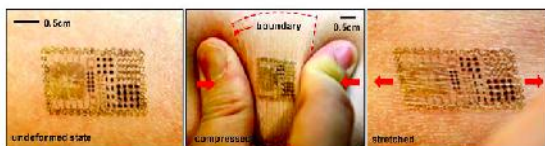
CTRI Pre/post-doctoral Training Program (TL1)

- 100 enrollees since 2010
- 3 month (8 positions) and 1 year (10 positions) curriculum for MD and PharmD students
- 1 year program supports MAS degree
- Recent changes:
 - Expand to UC Riverside
 - New tracks with MAS in Clinical Research program
 - New MS degree in Drug Development Science
 - Mentoring from K awardees
 - New post-doctoral trainees for team science (2 positions)



CTRI science: Disruptive innovation

Stamp-sized patches of circuits, sensors, and wireless transmitters to monitor the brains immediately after birth
Todd Coleman—engineer
MJ Harbert—pediatric neurologist



Disruptive innovation—Tricorder XPRIZE

International teams compete for novel home-use diagnostic device