

ELEMENT D - MODULE 1

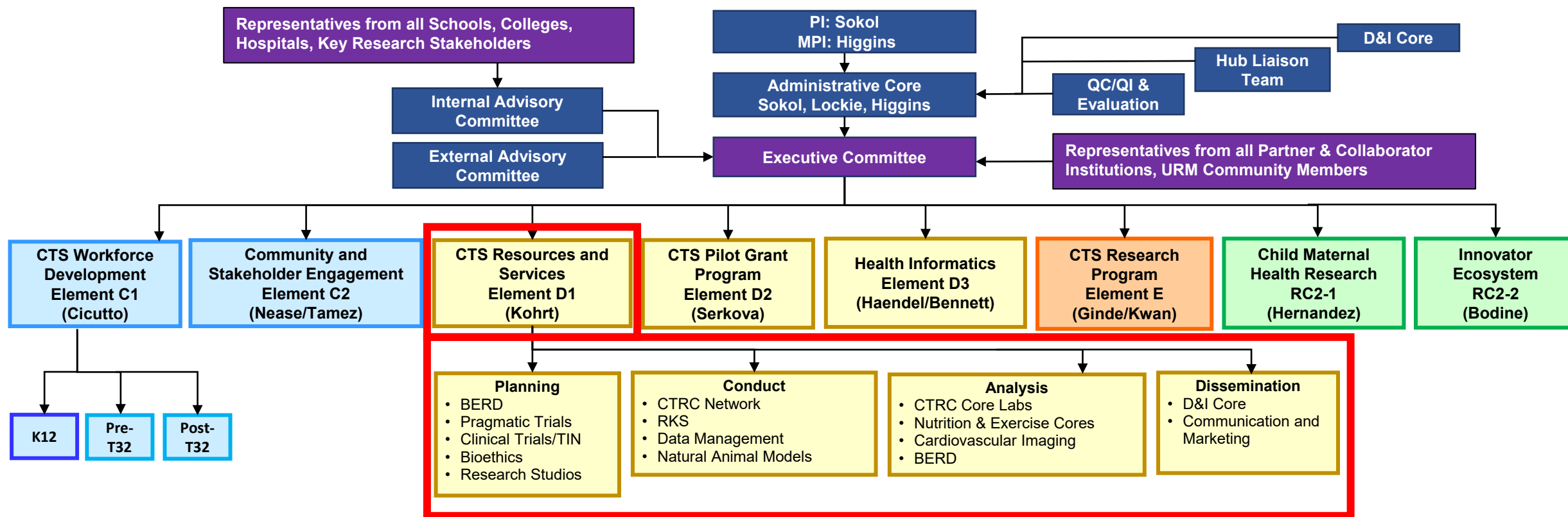
CTS RESOURCES & SERVICES

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Strategic Goals

1. Provide **supervisory oversight** of R&S to facilitate equitable access and ensure that services enhance the efficiency, quality, and safety of CTR protocols
2. Develop expertise and capacity to support the **design of virtual and real-world clinical trials**
3. **Accelerate the start-up and completion of CTR** by addressing barriers that impede progress, building on lessons learned from the rapid implementation of COVID-19 protocols
4. Ensure R&S operations can **respond to urgent public health emergencies** by pivoting to meet new needs and overcoming emerging roadblocks quickly and efficiently
5. **Enhance recruitment and retention of diverse research participants** by utilizing new targeted recruitment tools and deploying novel models to encourage research participation across the lifespan



Approach and Innovation: Goal 1

Goal 1: Provide supervisory oversight of R&S

Approach: Streamline and align processes across CTRC Cores and Sites

A new Research Operations and Strategic Integration (**ROSI**) service will conduct process mapping, evaluate workflow, and document audits

ROSI will assemble a user advisory board of stakeholders to inform and prioritize process improvement projects

Approach: Facilitate collaboration between veterinary and human medical scientists to leverage naturally occurring animal models of human disease through a Natural Animal Models Core

Develop guidance for a new veterinary 'smart IACUC' for multi-center trials, best practices for veterinary bioarchive management, and promote training and communication efforts in One Health



Approach and Innovation: Goal 2

Goal 2: Develop expertise and capacity to support virtual and real-world (pragmatic) clinical trials

Approach: Establish a Virtual Clinical Trials Core

Develop central resources that facilitate high quality and safe pragmatic clinical trials conducted in home or hospital environments

Leverage lessons learned, materials, and support from Element E (PEET)

Approach: Utilize the CCTSI Pragmatic Trials Navigation Service to provide self-guided resources, education, and targeted consultations

Approach: Utilize the D&I Research Core for education, mentoring, and collaboration for dissemination and communication



Approach and Innovation: Goal 3

Goal 3: Accelerate start-up and completion of CTR

Approach: Align RKS and CRIO resources to provide rapid data access and tracking of study milestones

Develop novel dashboards to monitor protocol start-up and progress for both administrative/regulatory staff and PIs

Approach: Establish a centralized IND/IDE support office

Approach: Merge two CTRC Core labs to expedite feasibility review, study start-up, and sample tracking

Approach: Introduce a Veterinary Clinical Trials Coordinator at CSU to support multisite clinical trials and provide regulatory, budgetary, and logistical support



Approach and Innovation: Goal 4

Goal 4: Ensure that R&S operations can respond to urgent public health emergencies

Approach: Utilize the new ROSI service to reduce redundancy and create unified workflows across CTRC Cores

Simplified, streamlined workflows and documentation will facilitate rapid and transparent navigation and integrated utilization of CTRC Network resources during a public health emergency

Approach: Create a single, overarching CTRC IT governance plan

Consolidated access to protocol information and operational data will expedite study startup and implementation by CTRC Cores



Approach and Innovation: Goal 5

Goal 5: Enhance recruitment and retention of diverse research participants

Approach: Implement and expand the Older Adult Research Specialist (OARS) program and Research Roadshow to encourage research participation by older adults

Utilize the life experience and skills of older adults to support the recruitment and retention of older research participants

Approach: Increase research participation by underrepresented populations across Colorado, including in rural regions

Leverage newly developed research tools in the UCHHealth EHR to encourage research participation by underrepresented populations

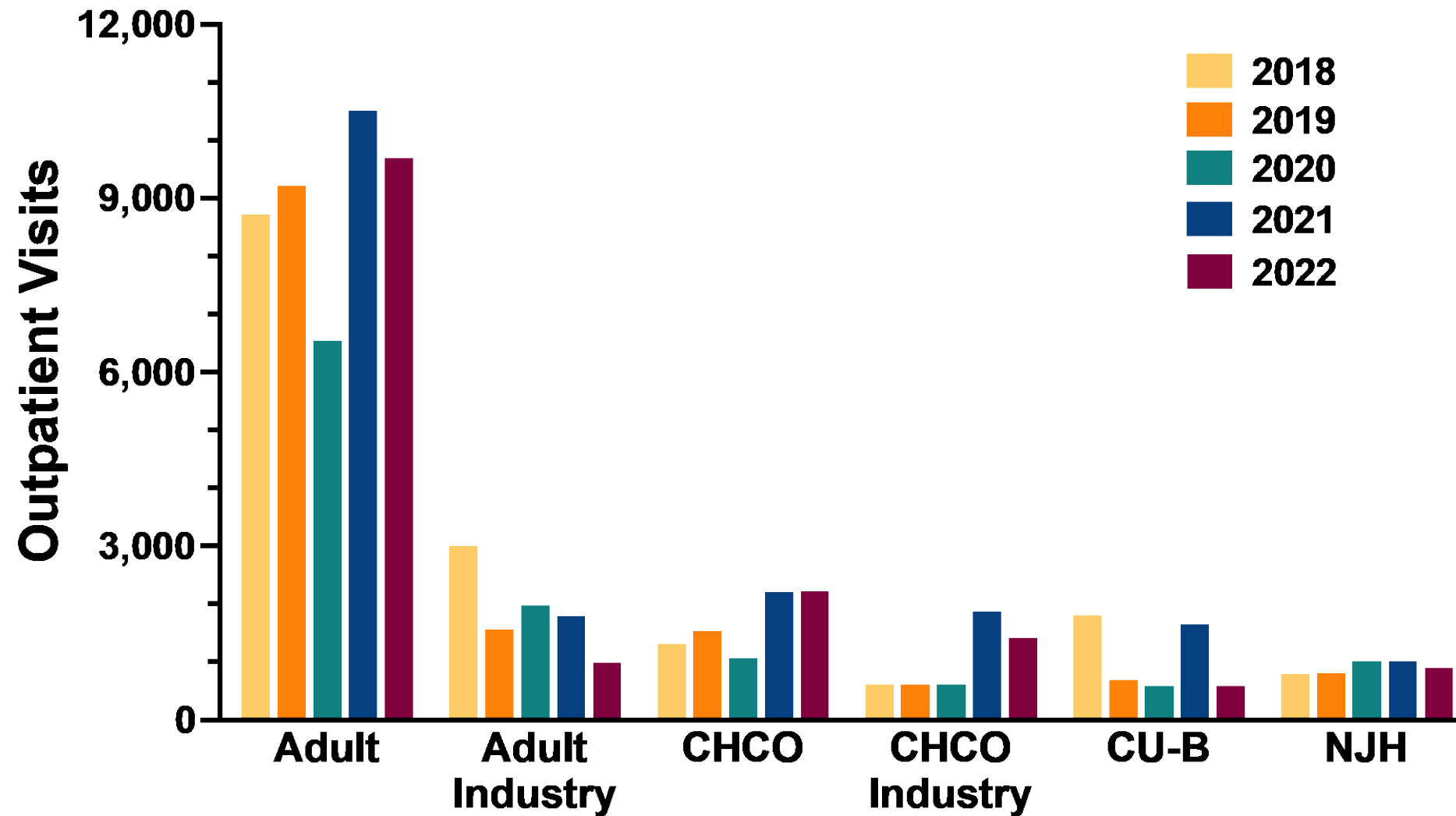


Expected Outcomes and Impact

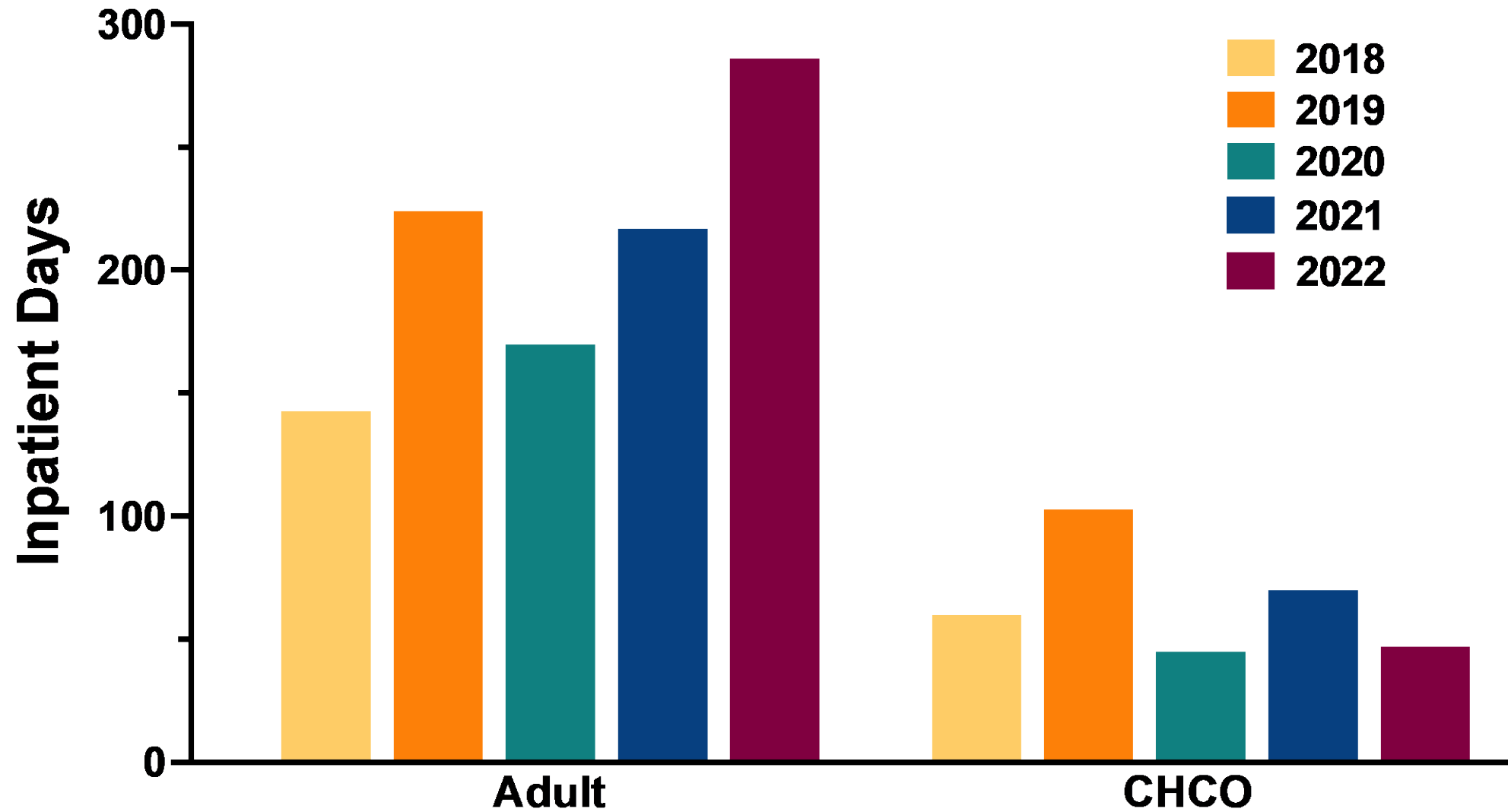
- Expected outcomes and impact of each Resource and Service will not be presented because of time constraints
- CTRC Network metrics are presented because it is the most widely used Resource; extent of utilization reflects impact
- The Research Operations and Strategic Integrations (**ROSI**) program will develop strategies for quality and process improvement across R&S in the next award period as specific roadblocks emerge from
 - Stakeholder advisory committee
 - User satisfaction surveys



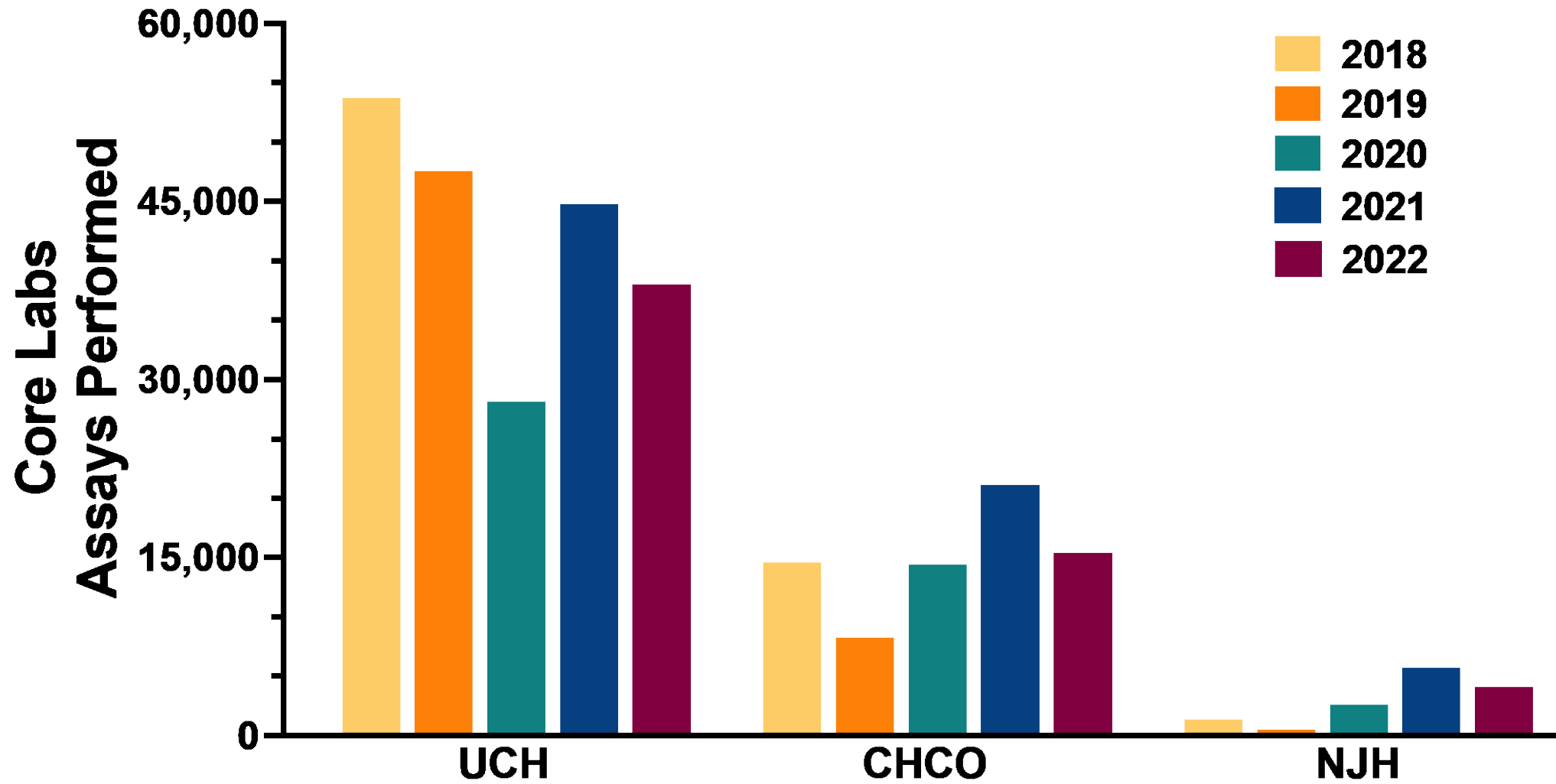
CTRC Outpatient Visits



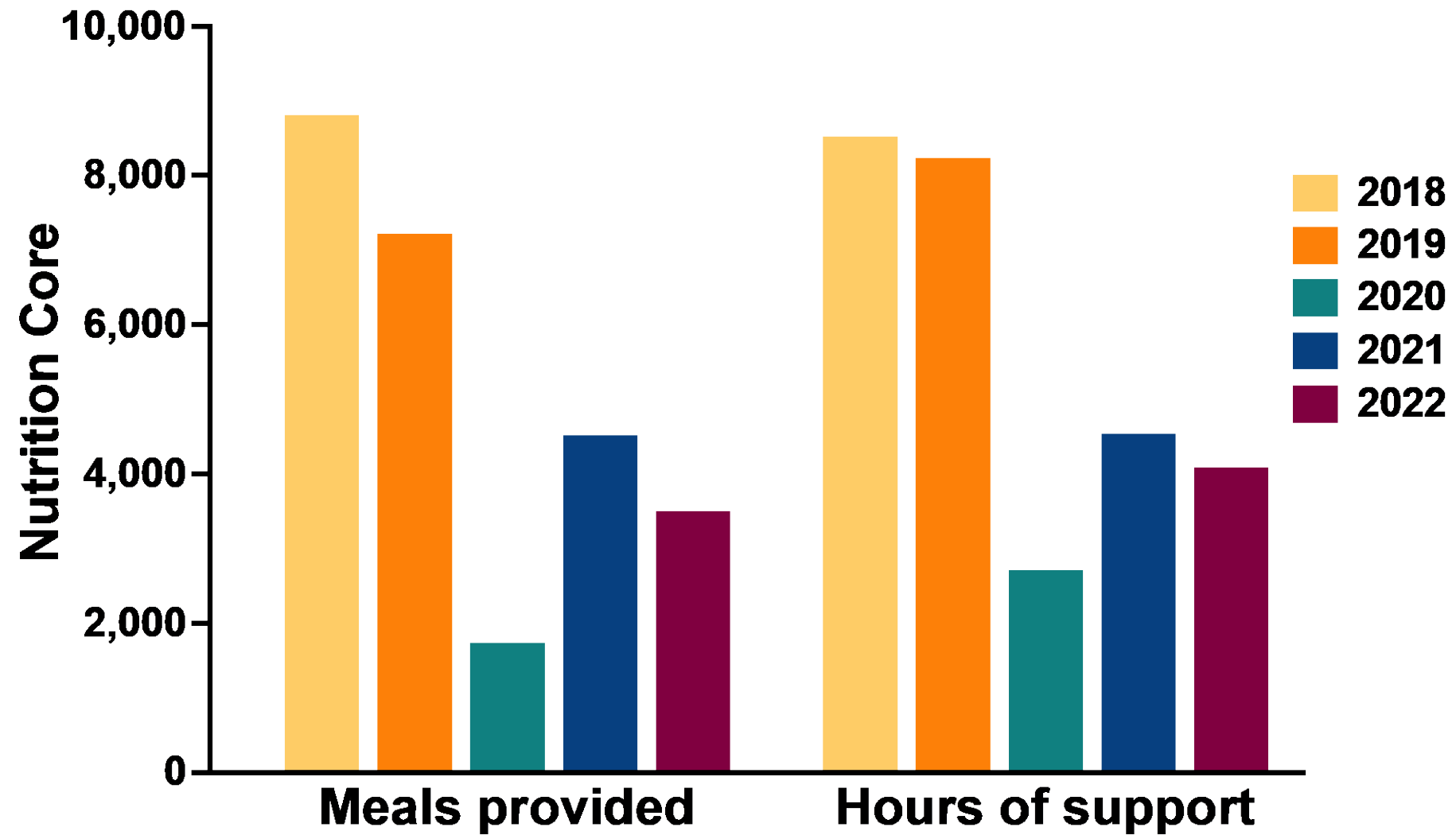
CTRC Inpatient Days



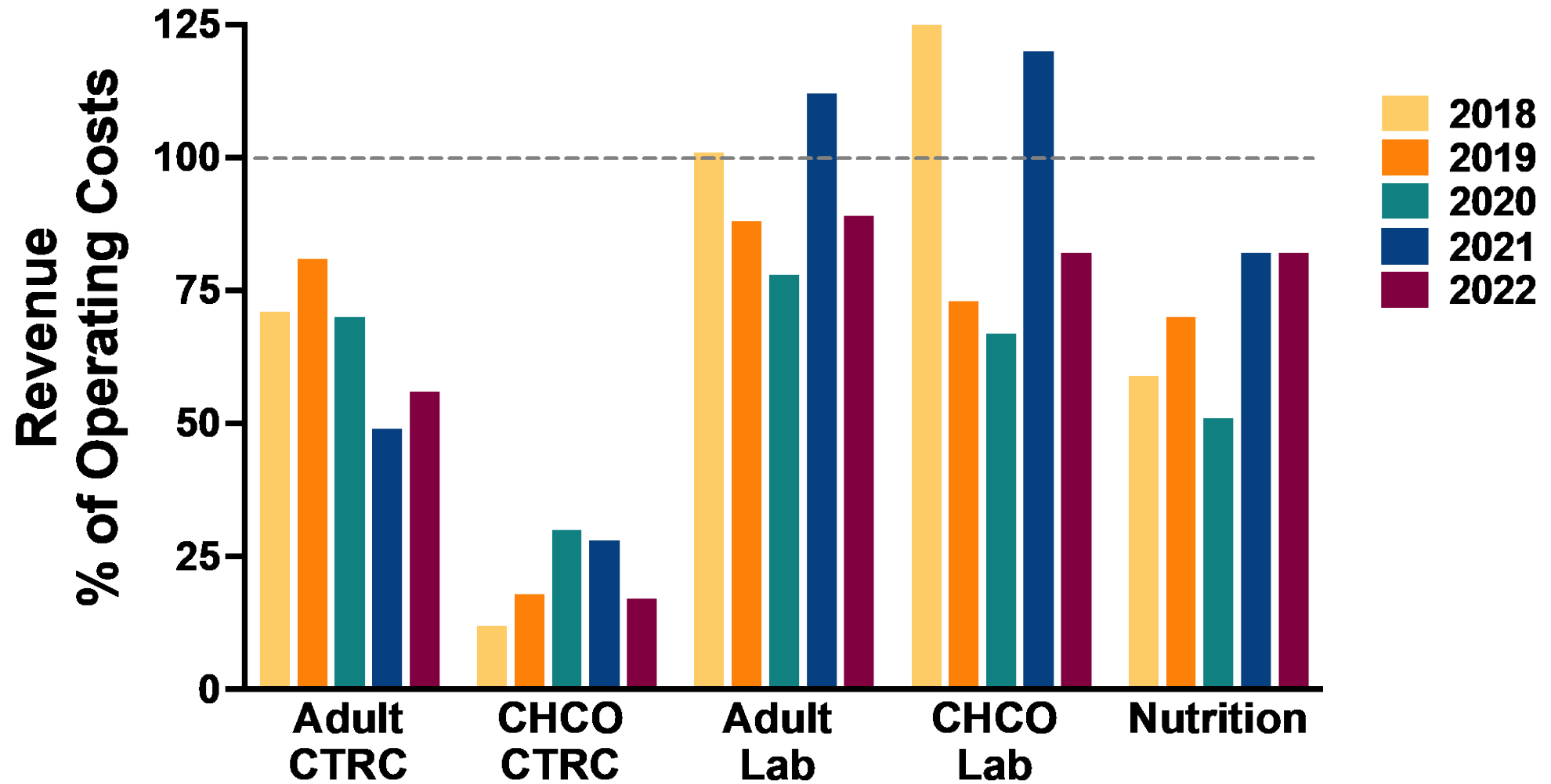
CTRC Core Lab Tests



Nutrition Core Activity



CTRC Revenue



MicroGrant Program

	UCH				CHCO			
	Budget	Awarded	Spent	# Awards	Budget	Awarded	Spent	# Awards
2018	\$250,000	\$177,000	\$126,050	9	\$250,000	\$204,000	\$45,206	9
2019	\$250,000	\$259,000	\$142,692	13	\$250,000	\$284,000	\$227,650	15
2020	\$250,000	\$177,500	\$122,744	9	\$250,000	\$141,000	\$102,697	7
2021	\$250,000	\$273,500	\$118,811	14	\$250,000	\$192,500	\$148,933	11
2022	\$250,000	\$110,000	\$108,946	5	\$250,000	\$78,500	\$83,227	5
Program Totals	\$2M	\$2.03M	\$1.27M	110	\$2.45M	\$1.6M	\$1M	97



DEIA and Health Equity

- Goal 5 of the Resources and Services Module - focused on enhancing diversity of volunteers enrolled in clinical trials
 - **Enhance recruitment and retention of diverse research participants**
- Research Ethics consultations - require every consult to address DEIA and issues of justice/fairness
- Workforce diversity – heightened requirements for hiring practices, assembly of panels/speakers/etc
 - **4 of 5 keynote speakers for Annual Research Ethics Conference were from underrepresented groups**



DEIA and Health Equity

- Pragmatic Trials Navigation Service
 - **Engaging partners from diverse communities in pragmatic trials is essential for generating evidence on effective strategies for promoting health equity**
- D&I Research Services
 - **D&I training addresses equity-oriented contextual factors in adoption and implementation of evidence-based practices**



Metrics and Evaluation

- Specific metrics vary across each Core Resource
- Evaluation is based, in part, on
 - **Needs Assessment Survey** – conducted every 3 years; distributed to members and non-members
 - **User Satisfaction Survey** – conducted annually; distributed to all Core Resource users
 - **Stakeholder engagement**



Integration and Collaboration

- Some Cores, by design, have limited integration across CCTSI components
 - **Cardiovascular Bioimaging activities are integrated with the CTRC Network**
- Other Cores have extensive integration and collaboration
 - **Pragmatic Trials Navigation Service has integrations with the BERD, Informatics, D&I, CEHE, and TIN Hub Liaison Team**



EAC Critiques

- Evaluate the effect of the microgrants for scholars. If it appears to be beneficial to early career scholars, consider expanding the program.
- Keep an eye on UC-Boulder CTRC service use and consider implementing a plan to increase usage.
- Integration of Special Populations: This effort may benefit from being partnered upstream with an effort to ensure that these clinical protocols have an appropriate age range for the condition under study.

