



2022 SUMMER CPE SYMPOSIUM: WHAT'S HOT IN HEALTHCARE

# Clinical Trials Program

## As a New or Expanded Service Line

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Session 4 | July 28, 2022

# Presentation Overview

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- Industry Financial Landscape
- Value of Clinical Research
- Foundational Elements of Success
- Assessing Feasibility of Implementation or Expansion

# Clinical Research Industry Financial Landscape

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# National Funding

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- Every year, billions of dollars are dedicated to medical research through Federal, private and industry agencies
- Funds earmarked for research are experiencing consistent, stable growth annually
- Research funds provide an added revenue source for healthcare organizations
- Top funded areas align with hospital service lines

# NIH Funding Growth

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## 2022 Budget

- \$41.7B – increase of \$2.6B from 2021
- \$4.8B additional over the next 8 years through 21<sup>st</sup> Century Cures Act

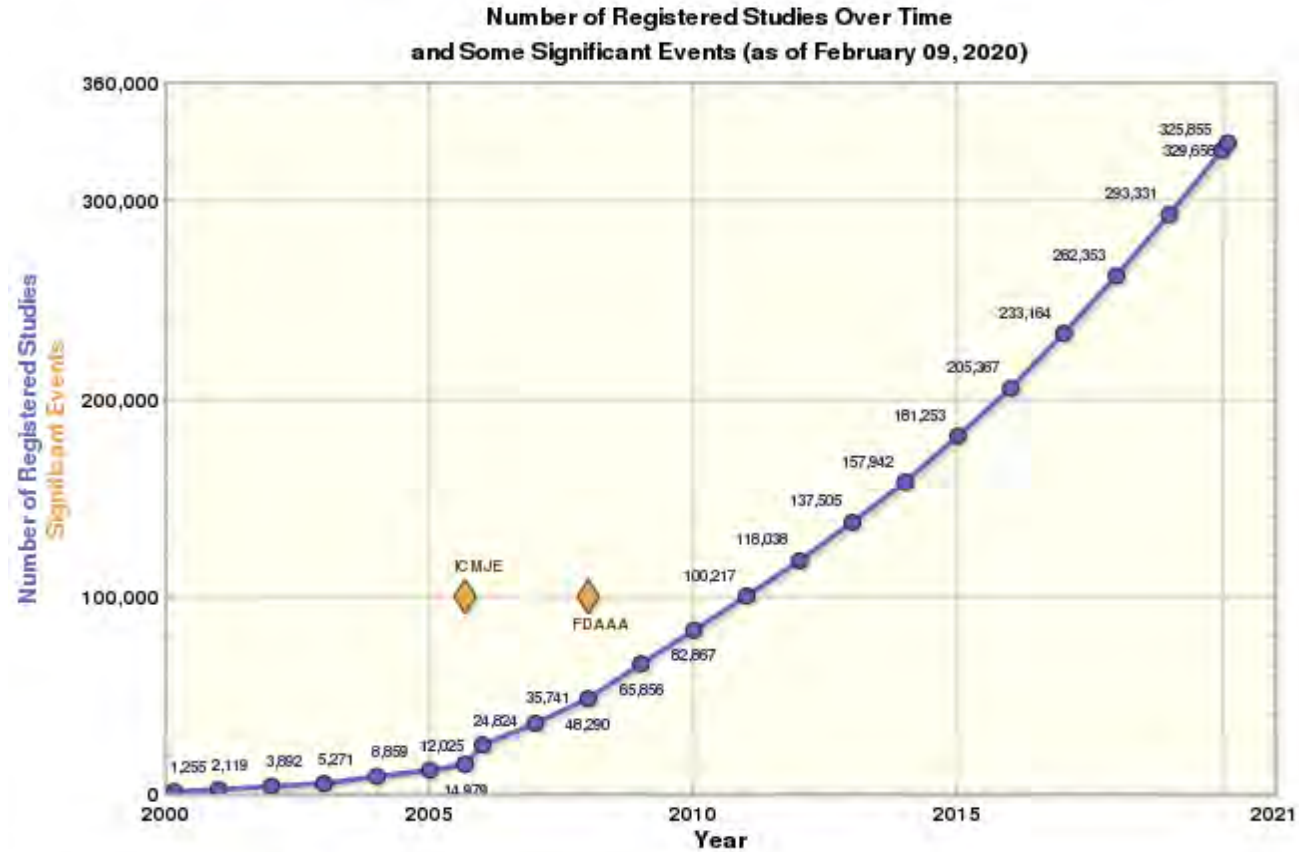
## Top Funded Specialties

- \$7.4B                      Cancer
- \$5.8B                      Infectious Disease, Allergy (Aids, Influenza)
- \$3.6B                      Heart, Lung, Blood
- \$3.6B                      COVID
- \$3.5B                      Aging (Alzheimer's, Dementia)
- \$2.4B                      Neurological Disorders (Stroke, Addiction, Opioid Misuse)
- \$2.1B                      Diabetes, Digestive, Kidney
- \$2.0B                      Mental Health

**Representative – not a comprehensive listing of Federal funding opportunities**

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# Industry Sponsored Clinical Research Growth



Source: <https://ClinicalTrials.gov>

- 2019 North America Clinical Trials Expenditures = \$5.65 billion
- Projected 2027 = \$40 billion

# Private Agency Funding

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- \$116M = American Cancer Society
- \$189M = American Heart Association
- \$109M = Michael J. Fox (Parkinson's Research)
- \$42M = Alzheimer's Association
- \$26M = Susan G. Komen Foundation
- Others:
  - Leukemia & Lymphoma Society
  - American Lung Association
  - March of Dimes
  - Muscular Dystrophy – and so on...

**Representative – not a comprehensive listing of private funding opportunities**

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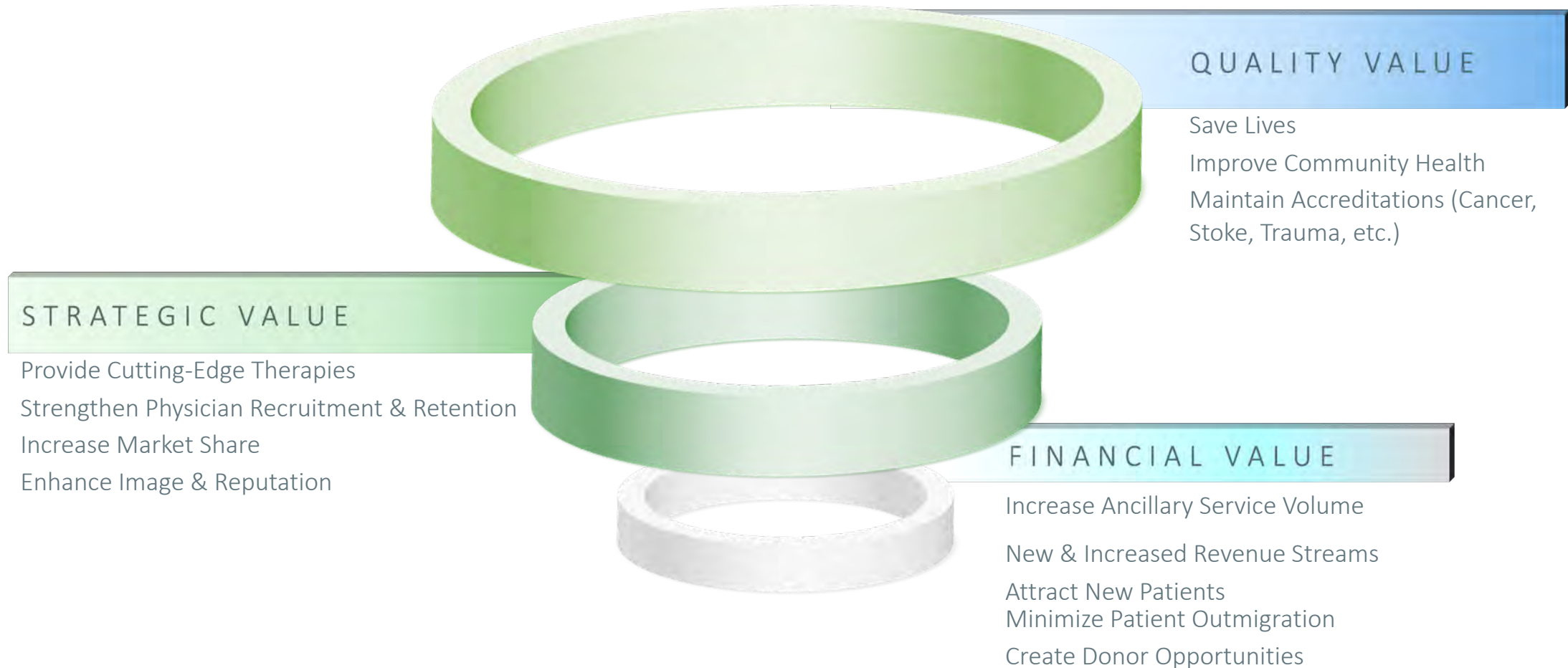
# The Value Proposition

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# The Value of Clinical Research to an Organization



# The Impact of Research – Patient Perceptions



89% of respondents

perceive that a clinical research program is associated with a higher tech/innovative community hospital



75% of respondents

indicated that participation in research is an important factor to consider when choosing a physician



81% of respondents

feel the presence of research is a significant consideration when choosing a hospital

# Downstream Revenue Impact of Research

## Development of a Research Network Example Revenue Impact on Hospitals



\*Downstream revenues are revenues outside of trial protocol revenues. They included both plan payments and patient liability (copays / co-insurance) for all services received during the treatment episode, whether related or unrelated to the care for the patient's cancer. We controlled for patient's age, gender, and the prior history of cancer in calculating the total episode costs.  
Source: <https://www.ama-assn.org/practicing/education/industry/2015/01/01/ama-research-revenue-report>



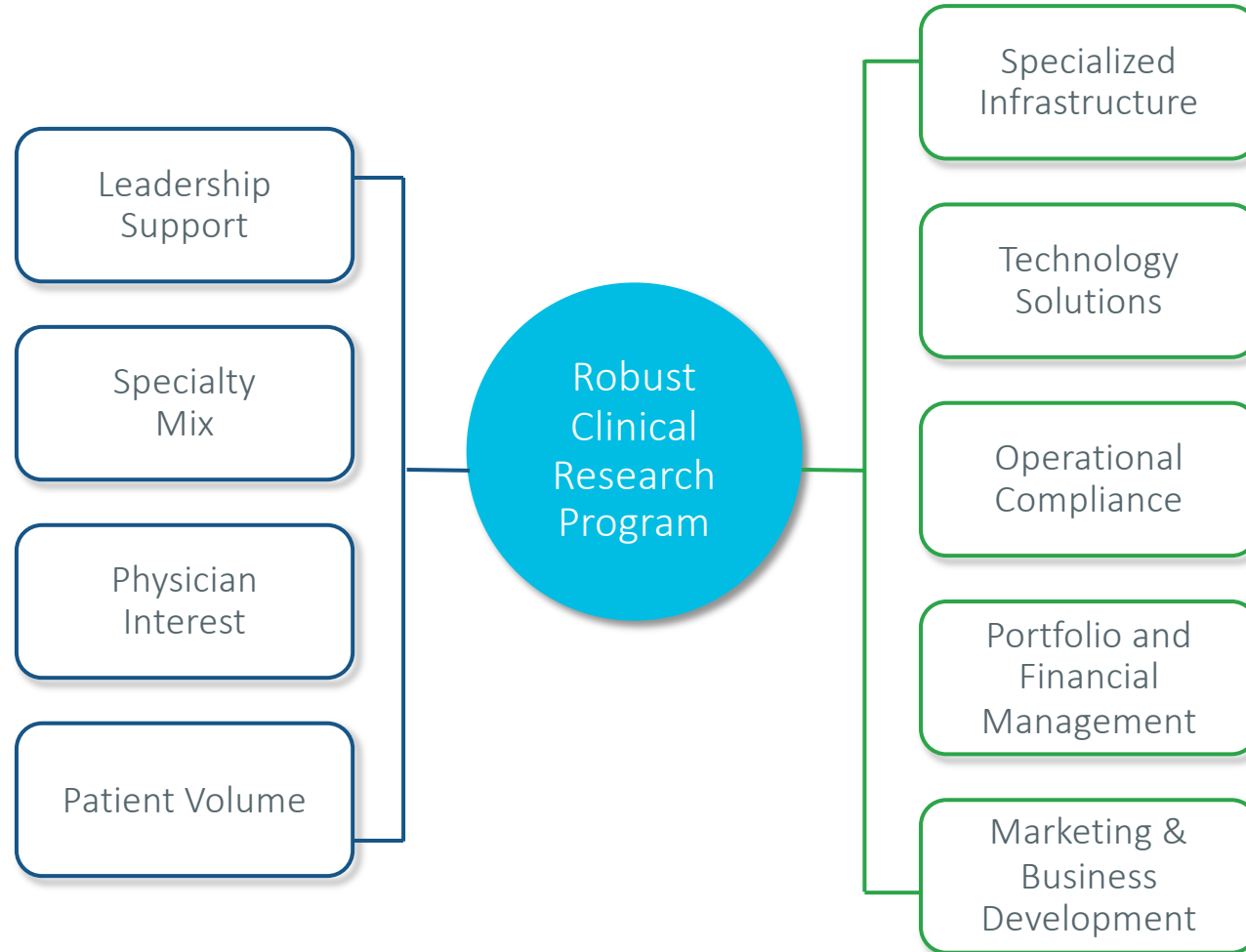
January, 2015 | © Kurt Salmon | 13

# Foundational Elements for Success

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# Foundational Elements



*Tracking Performance Metrics is vital to monitor and track success of the operation*

# Top 10 Key Performance Metrics

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- Number of specialties
- Number of investigators
- Trials procured/activated
- Timeline to trial activation
- Screening and enrollment
- Portfolio allocation
- Earned revenue
- Collected revenue
- Workload to staffing ratio
- Profit/loss

# Assess Feasibility of Implementation or Expansion

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# Feasibility Assessment

- Clearly stated goals - the “why”
- Analyze patient volumes by specialty and sub-specialties
- Gauge physician interest and capabilities
- Assess infrastructure needs
  - Organization
  - Staffing
  - Systems
  - Policy/SOP



# Feasibility Assessment (continued)

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- Financial Considerations
  - Three to five-year business plan/proforma
  - ROI 12-18 months after initial investment
- Compliance considerations
  - IRB
  - FDA
  - Coding and billing

# Discussion: Q&A

**PYA Tool/Checklist Available**

**Clinical Trial Program: Implementation/Expansion Readiness Assessment Checklist**

*The following addresses the elements of an effective clinical trials service line and considerations for implementation and expansion. It is not a comprehensive checklist, and additional factors may need to be considered depending on the maturity of an organization's clinical trials program.*

**1. Organizational Support**

- a. Is leadership looking for a new revenue opportunity?  
\_\_\_\_\_
- b. Is leadership looking for ways to enhance the organization's reputation and/or differentiate it from competitors?  
\_\_\_\_\_
- c. Is the organization looking for ways to minimize outmigration and attract new patients?  
\_\_\_\_\_
- d. Does the organization desire to achieve or maintain specialized accreditations requiring clinical trial participation?  
\_\_\_\_\_

**2. Patient Volumes**

- a. In what specialties/subspecialties does the organization have a critical mass of patients (i.e., oncology, infectious disease, cardiology)?  
\_\_\_\_\_
- b. What are the top five diagnoses seen by the organization?  
\_\_\_\_\_
- c. How many patients are seen annually per the top five diagnoses?  
\_\_\_\_\_

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