P41: THE RISKS AND BENEFITS OF HEALTHCARE CONSOLIDATION ON INNOVATION AND CLINICAL RESEARCH IN HEALTH SYSTEMS AND HOSPITALS

CONDUCTING DUE DILIGENCE AND THE COMPLIANCE RISK MITIGATION STRATEGIES TO HELP YOU SLEEP AT NIGHT

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Overview

Review

- Biomedical research promise and opportunity
- Health System and hospital motivators
- Trends in healthcare and academic consolidation and affiliation
- Risks for research mergers or acquisitions

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Overview

Discuss

- Considerations for organizations considering mergers or acquisitions of research programs, administration, or facilities
- Conducting due diligence on research programs with different operating models
- Risk assessment and mitigation strategies
- Case studies

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Promise and Opportunity

- The promise of clinical (human subject) research is to: Generate timely and practical evidence for drug and device development; Support medical treatment decisions; improve the delivery of care; and **Improve health.**
  - **HIV/AIDS:** Since the introduction of highly active antiretroviral treatment (HAART), the HIV/AIDS death rate has dropped **87%**
  - Since peaking in the 1990s, **cancer** death rates have declined **23%**
- The average cost to develop a drug (including the cost of failures): 2000s–early 2010s = $2.6 billion 1990s–early 2000s = $1.0 billion* 1980s = $413 million 1970s = $179 million
- Average time to develop a drug = 10 to 15 years
- Percentage of drugs entering clinical trials resulting in an approved medicine = less than 12%

Source: PhRMA 2016 Profile

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Opportunity for Clinical Providers

National Academies workgroup (then IOM) discussion paper: "Developing a Clinical Trials Infrastructure in the United States", May 2012

- **"…there are few clinical research structures in the United States that combine mature clinical trials infrastructure**, experienced staff, and established procedures **that also have access to large numbers of patients with a specific disease or disorder**"
- **"training and recruitment of less-experienced investigators who practice in settings that are relevant to the clinical questions** being addressed may improve the applicability of the results to the issues being studied. In addition to improving the ultimate applicability and uptake of clinical trial results, **these community-based investigators** could provide important expertise, in partnership with patients, in developing innovative clinical trial designs that efficiently study outcomes that are of interest to patients and the public

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Why do healthcare organizations conduct research?

- Mission
  - Improve Health of the Community
  - Better Outcomes
- Reputation
  - Expert Advice
  - Thought Leadership
- Finances
  - Reputation builds increased Market Share (Improve Margin)

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Healthcare Organizations

The promise of clinical research is to: Generate timely and practical evidence for drug and device development; Support medical treatment decisions; improve the delivery of care; and **Improve health.**

- How can academic medicine and healthcare ***successfully*** research and move a technology from idea to market with limited or no duplication of effort?
- Where are the unmet needs and how can they best be addressed?
- Where services can be consolidated, should they be?
- How do healthcare organizations best leverage their assets to improve health & cure disease?
- Where to Buy? Lease? Leverage?

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Market Trend: "Academic Health System"

Association of American Medical Colleges (AAMC) report entitled "Advancing the Academic Health System for the Future"

- Medical schools, universities and traditional Academic Medical Centers (AMCs) are in the process of implanting business plans for affiliation or partnerships with large "mega systems", regional players and provider networks
- Provides a number of recommendations, including increasing affiliations with clinical providers.
- Most important this may be where we first see the term "Academic Health System" used broadly.

Source: https://www.aamc.org/initiatives/patientcare/aphc/357864/academichealthsystem.html

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Drivers of Academic Health System Formation

- Movement from fee-for-service payment toward value based payment
- Need to achieve order of magnitude reductions in cost structures (of clinical and academic enterprises)
- Need to participate in consolidating markets and not be marginalized
- Need to continue to support teaching and research missions
- Need to manage population health, and
- Need to focus on the overall patient experience and overall societal health

Association of American Medical Colleges (AAMC) "Advancing the Academic Health System for the Future "
Consolidated Institutional Profiles

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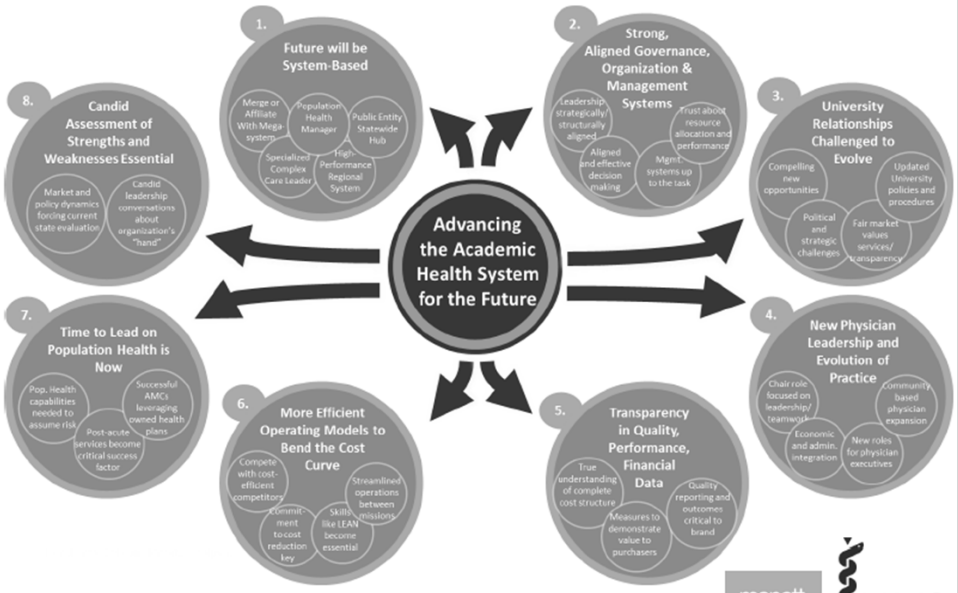
Major Themes – Advancing the Academic Health System for the Future



5 Association of American Medical Colleges (AAMC) "Advancing the Academic Health System for the Future " Consolidated Institutional Profiles

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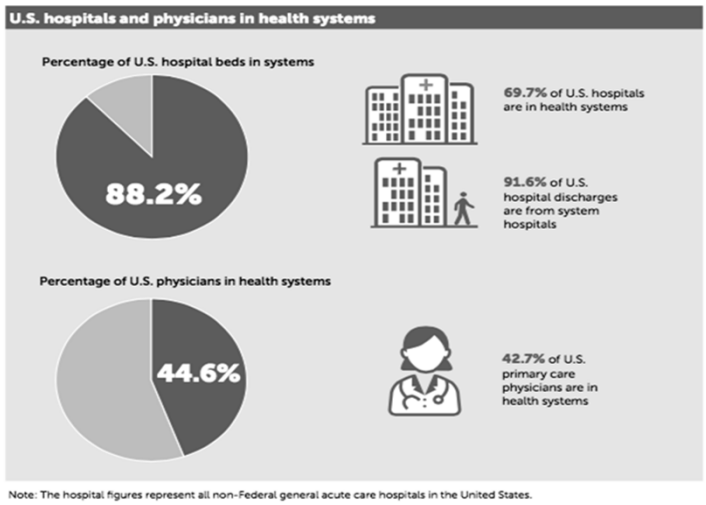
How many systems are there?

By the end of 2016, there were 626 health systems* in the United States.



Note: The hospital figures represent all non-Federal general acute care hospitals in the United States.

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OCT 02, 2018 | MORE ON MERGERS & ACQUISITIONS

Baylor Scott & White Health, Memorial Hermann announce merger

The systems include 68 hospital campuses, more than 1,100 care delivery sites, nearly 14,000 employed, independent and academic physicians.

RWJBarnabas will invest $100 million initially and more than $1 billion over the next 20 years on a public-private partnership with Rutgers University.

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Part of the partnership involves the construction and operation of a new clinical and research building for the **Rutgers Cancer Institute of New Jersey** as well as a new ambulatory care center, both in New Brunswick. The facilities should open in 2020.

A group will be formed in coming months with a unified clinical mission that complements the standards of teaching and research under a CEO to be named.

Details of the ambitious initiative were detailed in a Tuesday conference call with media, with highlights including:

- **The recruitment of leading clinical and academic leaders and faculty to build and expand the enterprise;**
- **The recruitment of approximately 100 high-caliber principal investigators by Rutgers over 10 years, to double the research portfolio;**
- **$10 million in financial support earmarked to encourage Rutgers medical students to remain in and**

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Market Trend: JVs, Consortiums and joint service providers to academic institutions

BRANY
www.brany.com

- Separate for profit LLC
- Founded and seed funded in 1998 by 5 academic medical centers in NY, fully operational and funded by external contracts
- Owned by Mt Sinai, NYU, Northwell and Montefiore
- 4 divisions BRANY Core, CITI training, Protocol Builder and HRP Consulting
- BRANY Core: provides single IRB review, contract negotiation and budgeting, medicare coverage analysis, invoicing and collections, a CTMS product, GCP audits and monitoring
- BRANY Core clients nationwide: 150+

PIER Consortium
http://pierconsortium.org

- Separate non profit
- 2018 start up, six regional health systems created a regional clinical trial system that will span New Jersey and Pennsylvania.
- Consortium includes Atlantic Health System, Drexel University, Einstein Healthcare Network, Geisinger including AtlantiCare, Main Line Health and Thomas Jefferson University
- Focus is on clinical trial management services

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Challenges & opportunities perceived by health systems, research institutes and universities

- Health Systems and Research Institutes want to be and be seen as equal partners with other collaborators and stakeholders in the drug and delivery process, not perceived as “just a site”.
- Health Systems and Research Institutes are under internal (consolidations and affiliations) and external pressures (clinical market forces) to be more efficient in clinical research strategy and operations.
- Health Systems and Research Institutes believe that partnerships with entities outside of the healthcare sphere will be critical to managing data needed for the next generation of clinical research studies, including clinical trials.
- Universities, Medical Schools and Research Institutes believe that partnerships with large health systems, large clinical provider networks and regional health providers will be central to their continued success and clinical research growth strategies.

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Potential Risks

- Mergers and acquisitions at the health system or hospital level are often made based on clinical objectives with limited understanding of how that might affect research operations or strategy, if there is a research strategy.
- Lofty research goals might be defined, but the practical operational details of how to achieve those goals are often difficult to define or to gain acceptance.
- There is little practical guidance available and regulatory changes and uncertainty make it difficult for planning.
- Culture and business models between academics and clinical providers may not align: “Discovery Research” versus “Applied Research”.

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Potential Risks

- Some of the traditional research administrative services, offices, or official job titles at academic medical centers or universities may not exist, or may not be well coordinated or defined in provider settings.
- Oversight of and accountability for research programs in health systems are often highly de-centralized, whether by department, facility or region.
- Central Business offices find it difficult to monitor and ensure both compliance and operational efficiency for research.
- There is often no central financial statement for research to manage and monitor financial and operational performance or if one is created it's a manual effort.
- As a result of the above many health systems are moving towards increased centralized structures, requiring changes in SOPs, business process, financial systems, HR, etc.

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Reading the Tea Leaves

- Be connected and knowing what's coming
- Be part of the due diligence process/team
- Perform due diligence
  - Develop research questions
  - Include research materials in data requests
  - Integrate research questions in main survey
- Schedule meetings and any follow-ups

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Sizing Up the Other Organization's Research

- Determine the type & size of the research
  - Lab, animal and/or human
  - Funding (e.g., internal, state, federal, private, or industry)
  - # of research studies in each area and extent
    - Local, national and/or international
  - Locations of research
  - Setting (e.g., outpatient, inpatient, community based, mixed, academic)
- Determine any critical or large research programs
- Any other activities or programs?
  - Manufacturers, FDA related risks
  - Start-ups, JVs, etc.
  - Industry partnerships or large scale collaborations

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Sizing Up the Other Organization's Research

- Are any of their programs accredited?
  - Human Research Protection Program (HRPP) Accreditation
  - Assessment and Accreditation of Lab Animal Care (AAALAC)
- Assurances?
  - Federal Wide Assurance (FWA) – human subject research
  - Office of Research Integrity – Public Health Service (PHS) supported research
- Regulatory burden?

What are implications of acquisitions and mergers on accredited programs?

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Determining the Research Infrastructure

- Research Leadership, institutional official, Provost, Dean, etc.
- Research Administration
- Research support: e.g., Clinical Trials Office, Tech Transfer, Environmental Health & Safety, Core Services, Research IT, etc.
- Sponsored programs, grants management & finance
- Research Compliance Officer, Research Integrity Officer & other oversight
- Regulatory committees & offices:
  - Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), Radioactive Drug Research Committee (RDRC), etc.
- Use of consultants or 3rd parties
- Tied to graduate medical education programs

What are implications of the above being centralized versus decentralized?

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Determining the Research Infrastructure

- What else is in place to support research?
  - Technology, software and data management, administration
    - Research informatics and/or security teams
  - Billing systems and processes
  - Policies and procedures
    - Research specific or broad
    - Compliance/Integrity related: HIPAA (for covered entities), COI, research misconduct, etc.
    - SOP driven or largely unwritten?
  - Training and education
- Institutional approval processes and support

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Background Research

> Do online research on the program and evaluate relationships and affiliations

> How compliant is the organization?

- Look up FDA warning letters
- ORI cases

> Media headlines

> Any other organizations that show up on their web site that you didn't know about?

> Any programs that are strong?

What are implications of inspection findings?

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Meeting the Right People

Key things:

- In-person meetings are valuable
- Find the right people to talk to

Don't assume that:

- The right people are in the initial meetings
- The people you talk to have a good understanding of the ongoing research
- The questionnaires are completed correctly
- You'll obtain all of the information after one meeting

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It's Official, Now What Do You Do?

Culture is everything

> The unloader

> The keeper

> The Jack of all trades

> The big corporate takeover is here!

> Everything is on paper, in person or blessed by the godfather

The people matter

> Matching your team with their culture

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It's Official, Now What Do You Do?

> Timing is everything

- Transition timeframe
- Resolving issues
- Establishing personnel
- Adoption or merging of policies
- System integration
- Centralizing resources

> What's the plan?

- Be flexible and know it can change

What are implications of operating under different policies?

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Preliminary Assessments

> Start broad, but risk matters
- Regulatory committees & oversight
- Research structure and organization
- Agreements with other entities
- Compliance and gap assessments

> How does their program fit into research accreditation?

> Determine if you have in-house resources or need consultants

> Develop a collaborative review plan, timelines and reporting

> Communicate with research & corporate leadership

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When to Implement Research Site Audits

> Establish a training program

> Develop a compliance work plan

> Ensure timing is appropriate
- Access to policies, systems, etc.?

> Focused reviews versus comprehensive

> Dedicated compliance team

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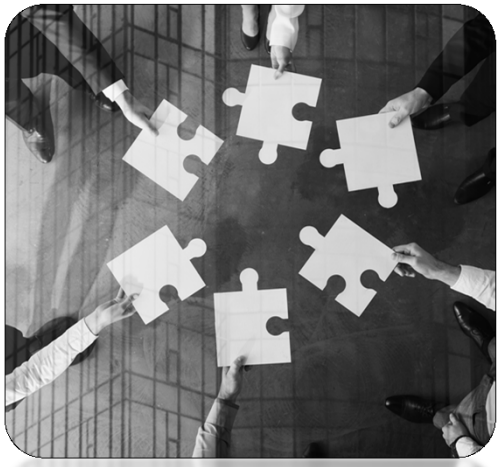
Going Forward

> Inclusion
> Auditing, risk assessments, work plans
> Ongoing education & training
> Involvement on system level committees, meetings and work



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Thank You

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