Effective Financial Management of Your Research Program

Health Care Compliance Association
Research Compliance Conference 2013

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Presentation Objectives

- Financial Realities of Managing a Research Program
- Shifting Landscape is Affecting Effective Financial Management
- Understanding How Various Research Settings Impact Financial Performance
- Key Strategic Considerations
- Key Operational Considerations
- Questions and Discussion

Financial Realities
### Financial Realities
Simple Math Underscores the Challenge

<table>
<thead>
<tr>
<th>Costs</th>
<th>Revenue</th>
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<tbody>
<tr>
<td>- Administrative Staff</td>
<td>- Indirect Cost recovery</td>
</tr>
<tr>
<td>- Laboratory Staff</td>
<td>- Per patient payments from Sponsors</td>
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<tr>
<td>- Coordinators</td>
<td>- Grants</td>
</tr>
<tr>
<td>- Office Space, utilities, overhead</td>
<td>- Contracts</td>
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<tr>
<td>- Laboratory Space</td>
<td>- Sub-contracts</td>
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<tr>
<td>- Coordinator Space</td>
<td>- Sub-awards</td>
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<tr>
<td>- Technology (billing, patient reg., acc't, db mgmt.)</td>
<td>- Deviations</td>
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<td>- Compliance Oversight</td>
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<tr>
<td>- Policy development / enrollment</td>
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<tr>
<td>- Regulatory</td>
<td></td>
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<tr>
<td>- Marketing / Patient Recruitment</td>
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<tr>
<td>- Training</td>
<td></td>
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<tr>
<td>- Continuing Education</td>
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<tr>
<td>- Outreach</td>
<td></td>
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<tr>
<td>- Unbudgeted screen failures</td>
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<tr>
<td>- Lost Critical Revenues</td>
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<tr>
<td>- Research Discounts</td>
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<tr>
<td>- Strategic planning and time taken away from other ventures</td>
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</table>

- Many of the revenues are based on recouping expenses budgeted at cost or with only marginal premiums.
- Many institutions negotiate IDC at levels below actual overhead.
- Few organizations proactively deploy advancement professionals to raise money for research endeavors.
- An institution’s ability to just break even with research, is difficult.

### Financial Realities
Eyes Wide Open

- The pathway to financial solvency depends upon many things:
  - Expectations
  - Resources
  - Governance / Leadership
  - Patient engagement
  - Physician engagement
  - Process optimization
  - Partnerships
- There needs to be agreement on the strategy and a decisive plan for how to execute.
- The best organizations understand the risks and develop financial plans to overcome them.

### Financial Realities
Embrace the Reasons Why Your Institution Chooses to Nurture Research

- Participation in the advancement of science.
- Enhancement of a clinicians understanding, diagnosis, treatment, and prevention of disease.
- Providing your patients with access to new medications.
- Becoming a so-called “Center of Excellence”.
- Advancing the mission (i.e., education, community benefit, research).
- Positive buzz, publicity, halo effect, brand, perception, reputation.
- Advancing the professional profile of clinicians.
  - Publication with meaningful professional organizations.
  - Recruit more academic docs with new research ideas and experience.
Financial Realities
Embrace the Reasons Why Your Institution Chooses to Nurture Research

• Drive clinical programs by attracting patients who might not otherwise trek to your site.
• Keeping up with peers and other competitive influences.
• Generate diversified revenue streams.
• Quality improvement.
• Improve patient care.

Shifting Landscape
Exacerbates the Financial Challenges

Pace of Change is Rapid – External Factors

The decision to engage in research and build a program is being made in a much different environment than just five years ago. Or, as the case may be, five months ago:

| Conflict of Interest scrutiny |    |
| International collaboration |    |
| Competing institutions striving more into strategic growth of clinical research increases challenge of landing funding |    |
| Sub-recipient monitoring |    |
| Fraud and abuse, heightened enforcement agendas, Stark, etc. |    |
| Stem cells and other scientific controversy |    |
| Effort reporting, unique engagement issues, arrangements, consulting arrangements and other comp-related complexities |    |
| Clinical Trials selling |    |
| HIPAA issues |    |
| Compliance requirements with clinicaltrials.gov |    |
| Patent protections / intellectual property / tech transfer |    |
| Funding levels (already trending down and then the Sequester) |    |
Shifting Landscape
Pace of Change is Rapid – Internal Pressures

- Reduction in financial margin from clinical activities has made it difficult to fund research.
- No measurable outcomes and no accountability.
- Understanding about the mission, vision, direction, or interest in research by institutional leadership has become muddled.
- Absence of engagement by leadership. Uncertainty about where they need to invest.
- Dramatic increase (in some cases decrease) in the size and capability of research administration.
- Increased importance in cross-functional, inter-disciplinary translational research by the government has challenged programs that have not evolved.
- Need for more integration of research administrative departments.
- For anything interdisciplinary with a translational component, almost always, another institution will have to be involved.

Shifting Landscape
Taking Stock of Your Circumstances

- Is there a strategic plan for research?
  - Is it still relevant?
  - Is it still feasible?
- What research is important to your institution’s brand?
  - If research activity disappeared, what would be the impact on clinical services, reputation, patient satisfaction, physician engagement?
- What are the core pressures that your institution faces?
  - When was the last research risk assessment?
  - Do you have a research audit plan?
- If you were to self-diagnose what your institution does well, and sequentially doesn’t do well, what would you identify?

Understanding How Various Research Settings Impact Financial Performance
Research Settings

Different Organizational Dynamics Should Dictate One’s Research Portfolio

<table>
<thead>
<tr>
<th>Grants / NIH</th>
<th>Private</th>
<th>Industry</th>
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<tbody>
<tr>
<td>• Most prestige in research community.</td>
<td>• Often working with Foundations and donors.</td>
<td>• Usually large Phase II or III clinical trials.</td>
</tr>
<tr>
<td>• Considerable regulatory scrutiny.</td>
<td>• Flexible and open to negotiations with respect to how funds are managed and allocated.</td>
<td>• Can cover costs if effectively budgeted, billed, and managed.</td>
</tr>
<tr>
<td>• Attracts “big-name” physician-investigators.</td>
<td>• Visible in local community.</td>
<td>• Can increase patient base over time (advertising, word of mouth, clinicaltrials.gov).</td>
</tr>
<tr>
<td>• Often leads to large, multi-center grants and cooperative initiatives with other institutions.</td>
<td>• Limited prestige but can help underwrite costs for seed funded projects.</td>
<td>• Portfolio can be built with PIs who have less experience.</td>
</tr>
<tr>
<td>• Complex financial requirements.</td>
<td>• Can help attract young PIs who are interested in research as a part of a start-up package.</td>
<td>• Requires more training than PIs often expect.</td>
</tr>
<tr>
<td>• Venue specialized skill sets.</td>
<td>• Hard to build.</td>
<td>• Unanticipated ethical issues, COI, misconduct, etc.</td>
</tr>
<tr>
<td>• Hard to build.</td>
<td>• Large administrative functions.</td>
<td>• ‘Easier’ to build and growth can be rapid if Investigators are aggressive. compliance departments must be nimble and able to scale up quickly.</td>
</tr>
<tr>
<td>• Large administrative functions.</td>
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Research Settings

Different Organizational Dynamics Should Dictate One’s Research Portfolio

Investigator Initiated (Industry Supported)

• Great for new faculty or physicians at any level of training but they need someone experienced to move it along, help design projects as needed, staff to help with paperwork, etc.
• Companies will fund small studies for investigators at hospitals and clinics.
  - In these investigator-initiated industry studies, the funds will come from the company.
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  - Companies will fund small studies for investigators at hospitals and clinics.
• Company is not generally the Sponsor so they will not be accountable for any part of conduct and also may tighten up on indemnification since they will not have oversight.

Investigator Initiated (Institution Supported)

• Small projects (observational, outcomes, students, nursing) are either likely not funded or there are small amounts of institutional funding.
• Every institution should support these studies financially and otherwise.
• They stimulate the research environment at low cost - get people excited in research since it is now a part of your mission.
• These studies can give leadership the opportunity to assess interest and skill level of investigators, departments and staff.

Research Settings

Financial Failure Can Be By-Product of Overly Ambitious Research Strategy

• What is meant by a research PROGRAM?
  - A great clinical trials portfolio is still not a research program.
  - In multicenter clinical trials, local PIs are recruiting patients onto a large study of someone else’s design. This does not teach someone how to do research.
  - A good clinical portfolio of industry and cooperative group clinical trials is excellent for patients and can help with community outreach and bring local attention to your institution especially if you are more than 30 miles away from an established center.
  - That being said, from a financial standpoint, if this is the goal – it is easy to achieve and relatively short-term. It will support itself eventually, but it must be looked at as a cost center and not a department.

A Research Program can design its own studies for implementation locally and nationally, recruit successful investigators at all levels and have the infrastructure to keep them there so that they can contribute to the robustness of the program. Ultimately, this is the best way to survive long-term.

This is as opposed to being a clinical site on someone else’s studies.
What kind of research program do you want?

- Clinical trial portfolio in a few areas:
  - Relatively easier than a grant-funded program.
  - More likely to be financially stable at a faster rate.
  - Will not bring prestige in the medical community or improve recruiting but it will broaden the patient base which will improve finances.

- Comprehensive research program:
  - Can be built in tandem and will be complimentary to clinical trial portfolio.
  - Success will bring prestige in the medical community and will help recruiting.
  - Requires partnerships with academic institutions.

Research Settings
Financial Failure Can Be By-Product of Overly Ambitious Research Strategy

Research is a challenge in all environments.

- University hospital: 'Own' the research and the hospital
- Community hospital (non-profits)
- Hybrid:
  - University – Corporate Hospital
  - University – For-profit Clinic
  - University – Non-profit Hospital

Institutions aim too high too early.

- Institutions should embrace incremental growth.
- Academic centers have the most well known research programs which is largely a function of mission and strategic prioritization.
  - Smaller organizations should be realistic.
  - Combine at least two types of research funding from the start...some industry funded and some hospital funded is a common place to begin.
  - Think small, build competencies, make a few "first downs!"

University Hospital
Understanding the Imperatives that Drive Successful Research

Strategic Priorities:
- Research supports the mission.
- Investments in technology parks, incubators, and start ups.
- Identify and brand of institutions can be driven by the size, scale, and diversity of a the research portfolio.
- Investments in translational research.

Operational Characteristics:
- Large Pre- and Post-Award functions.
- Clinical research programs driven by administrative resources at the clinical department level.
- Protected time for researchers.
- Research centers of excellence, CTSAs, etc.
- Research labs, research pharmacies, other research core service centers.
- Dependency on IDC recoveries.
Community Hospital

- **Strategic Priorities:**
  - Provide catchment area/community with access to full continuum of health care alternatives and medical advances.
  - Attempt to gain a strategic advantage over peers.
  - Generate additional revenue and/or diversify revenue streams.

- **Operational Characteristics:**
  - Limited or no protected time means that medical staff must fulfill admin responsibility on their “own time”.
  - Centralized administrative infrastructure (in community hospitals with more mature programs).
  - Inefficient and mass-customized approaches to research (in community hospitals with less mature programs).
  - Sometimes see “pools” of research coordinators.

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Research Settings

Understanding the Imperatives that Drive Successful Research

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<thead>
<tr>
<th>Academic Medical Centers &amp; Universities</th>
<th>Community Hospitals</th>
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<tbody>
<tr>
<td>Focus on bench, basic and animal research</td>
<td>Greater focus on clinical research</td>
</tr>
<tr>
<td>Investigators hired and protected time granted for faculty to engage in research</td>
<td>Open medical staff vs. Closed med staff</td>
</tr>
<tr>
<td>Research part of the mission</td>
<td>Few community health systems have protected time for clinicians to pursue research opportunities</td>
</tr>
<tr>
<td>Pre-award and post-award administrative infrastructure in place</td>
<td>Organizational culture does not view research as a priority</td>
</tr>
<tr>
<td>Executive-level leadership for research enterprise</td>
<td>Limited administrative infrastructure</td>
</tr>
<tr>
<td>Sophisticated research accounting systems</td>
<td>Leadership for research programs are at the PI or the departmental level</td>
</tr>
<tr>
<td>Prevalence of federally sponsored research</td>
<td>Focus is on COOs and industry sponsored research</td>
</tr>
<tr>
<td>Publication of findings is expected</td>
<td>Less sophisticated approach to establishing the optimal portfolio of research to match strategic objectives</td>
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<td>Perception (and reality) of more bureaucracy compromises timeliness</td>
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Hybrid Model (i.e., academic partners with for-profit and non-profit hospitals)

- **Strategic Priorities:**
  - Hospital able to access a more mature research portfolio more quickly.
  - Stable partnership for comprehensive research.
  - Able to build a clinical trials program while raising private funds and encouraging small internal, non-interventional studies.
  - Some prioritize building a program around a single investigator.

- **Operational Characteristics:**
  - Diversity of the research portfolio means knowing the finance/accounting rules.
  - Physicians can get adjunct or visiting faculty appointments….IRB costs lower.
  - Often leverage the academic partner’s IRB.
  - Hospitals must be prepared to manage “someone else’s” research and bare the burden of others working with your patients.
  - Hospitals inherent the billing risk so need to confirm a good approach to participant billing compliance.
Hybrid Model (i.e., academic partners with for-profit and non-profit hospitals)

- University hospitals being purchased by a corporation yet research remains “owned” by the University.
- Anticipate and resolve potential post-transaction issues.
  - Duplicate and competitive committees with different expectations.
  - Argument about fund allocation between the two institutions.
  - No willingness of clinic operations to work with research even though it is an institutional mission.
  - Limited resources for faculty or research personnel. This also leads to duplicative and competitive staff and faculty. For example, which department “owns” the protocol? Mechanisms should be in place to handle this.
  - Unreasonable expectations (by everybody).
  - If the clinical entity feels that research is fine as long as it: 1) does not cost anything; 2) will not affect anything operational; and 3) that they will benefit from it…. failure is possible. There has to be joint buy-in at some level or it is just a waste of time, sanity and money.

Building a Financially Viable Research Program

Financial Viability

Strategic Planning / Operational Execution

- Strategy
  - Know why you are pursuing and/or nurturing a research program.
  - Understand the risks and benefits.
  - Dedicate the resources.
  - Look for partners.
  - Be realistic about timing and ROI.
  - Plan, review the plan, and review the plan again.
  - Build slowly or if already built, divest from underperforming research programs.

- Operations
  - Vet, examine, consider, and analyze each research opportunity.
  - Build financially responsible budget. Capture all costs.
  - Negotiate from a position of power. Enter negotiations armed with an MCA.
  - Bill sponsors, bill payors, debit study accounts….dedicate staff to manage the money.
  - Establish metrics and other measurables.
  - Train, retrain, and train again. Do not assume your Investigators know the rules.
Establish Realistic Expectations

- Be patient.
- Having a plan and the guts to carry it out.
  - Come out BIG – leadership announcements, institutional celebration, etc.
  - Establish a working group.
  - Set timelines.
  - Assign people to carry out work steps who can be relied upon.
- Confirm backing from institutional leadership.
  - Should be pervasive throughout an institution or joint institution.
  - There should be one message.
    - Research is important and it is part of the strategic plan.
    - Research will make the institution better.
    - Research will improve patient care.
  - Insist that these messages are included in speeches, writings, and other communications of Management.

Don’t Put Too Many “Eggs in One Basket”

- Do not exhaust resources to support a single researcher who may be bringing their portfolio based on a technology that Management believes will return considerable financial rewards.
  - Can create bad politics inside the organization.
  - Often the investment is in a good researcher who is good at getting awards but may not be the right person to “build” the program.
- Avoid over-investing in single technology
  - Assess clinical feasibility before focusing on business development and patents.
- Diversify your research portfolio
  - Industry trials may be able to support your personnel and trials costs and maybe a small percentage of Management costs.
  - Financial stability comes over time as reputation is built, start-up costs are saved, and there is more room for negotiation.
- Forego urge to sink considerable resources into junior clinicians or those with research backgrounds from their fellowships. Prioritize mentoring.

Confirm Buy-In From Entire Research Community

- Physicians
  - Must have confidence that they will be support and that their time invested in research pursuits will be rewarded.
  - Unless physicians choose to undergo the training and feel that they have adequate support services to draw upon, there will not be enough PIs.
- Patients
  - Must feel protected and not coerced.
  - Study options must be presented delicately.
  - Research portfolios should include studies that are relevant to the patient population.
  - Trust must be built within a community.
    - If enrollments are low, a program will fail.
- Administrators
  - Finance, PFS, and Patient Access administrators must be willing to either dedicate research specialists or train existing personnel to become their go-to person for research related issues.
Establish Expectations for Carefully Vetting Studies

- Confirm feasibility and scientific merit.
  - Take the time to carefully define the institutional breadth and depth of commitment.
    - Determine likelihood of accruing patients and set a realistic accrual goal.
    - Consider the implications of the study on institutional resources and patient population within the institutional catchment area.
    - Ensure that the study is aligned with the mission and vision of the institutional research program.
  - Clinicians and their associates must consider the opportunity using common sense and systematic evaluation to make the affirmative decision to move forward.
  - Formalize policies and procedures for clinical study evaluation and vetting.
  - Establish a committee charged with assessing feasibility often under represent stakeholders directly affected by the proposed research activity.

- Ensure that not accepting high risk studies or badly designed studies from private sponsors.
  - Not uncommon to be lured by a lot of money.
  - Often, it can be determined by carefully vetting a study that no one else will do the studies for safety reasons.
- Make the process appropriately rigorous enough to ensure that those who are dabbling will be dis-incentivized to participate.
- There must be buy-in by every department the protocol touches (radiology, pathology, nurses, physical therapy...everyone).
- Appropriately assess the target population. Do some mock screening.
  - If there are study assessments that fall outside of what is normally done in clinic, do a mock set up.
    - Run them as if the protocol was up and running.
    - Assess what space is needed and for how long, how does patient flow work?

Require MCAs

- The Rush case catalyzed many organizations to insist upon MCAs as the lynchpin for study initiation.
- By identifying early on what items and services can be billed to a 3rd party (patient, Medicare, private payors, etc.), MCAs can improve an organization’s ability to better negotiate payments from sponsors.
- MCAs can help in many, meaningful ways.
  - Determines if a trial is qualifying.
  - During preaward it helps keep the budget, ICF, contract and other key documents consistent.
  - During preaward it can be useful as a resource for scheduling and registration.
  - Clarifies items that are provided by the study sponsor or promises free of charge to the research participant.
  - Can help enable allocation of fixed fee revenue to other non-covered services.
  - Demonstrates a good faith effort of trying to determine billable vs. non-billable tests and procedures. This could be valuable in the event of an audit.
Financial Viability
Operational Considerations

Streamline Budgeting
- Migrate the institution to one budget template and confirm that the template being used captures all costs.
  - Mass customized approaches are bad business.
  - Leaving the responsibility in the hands of coordinators is usually a mistake.
- Ensure that you are capturing all costs including start up fees.
- Account for start up fees.
- Identify experienced professionals who can engage in budget negotiations that will lead to the most favorable financial terms possible.
- Establish a methodology for capturing PI fees, Coordinator fees, and other administrative fees.
- Establish a research CDM and/or a standard discount rate.
  - Leverage the MCA.

Evaluate IRB Effectiveness
- IRBs are often the target of complaint (e.g., "they’re slow," "they’re the bottleneck," "they don’t understand my research," etc.).
- If these criticisms are valid, then the impact on the research program from a financial standpoint can be significant.
- Efficiency is one thing but if there are compliance issues, the financial penalties can be severe.
  - But, how can you tell?
    - IRB records/documents/minutes lack organization.
    - No SOPs or some purchased/co-opted from other places but never customized.
    - No record of Internal Audit or Compliance or an external consultant having looked at IRB effectiveness.
    - Overly protective of the meetings. Are the meetings open to observation?
    - Limited training expectations.

Evaluate IRB Effectiveness
- More IRB red flags...
  - Lack of detailed review. Example: Do the IRB minutes reveal that 15 or 20 studies were reviewed in one meeting lasting an hour. Might be indicative of decisions taking place between chair and lead admin prior to the meeting.
  - Have not embraced the primary and secondary reviewer format.
  - Unwilling to consider use of a commercial IRB for national studies.
  - Investigators bully the Chair…and win.
Financial Viability
Operational Considerations

Are Human Subjects Adequately Respected, Protected?

- Absence of HRP policies and procedures can lead to investigations, misconduct, and undesirable external audits...all that carry a price tag detrimental to financial viability.
- Confirm that the following 'red flags' do NOT exist:
  - No patient ever refuses a study – 100% enrollment (more than 10% would be odd)
  - There are advertisements to the public specifically for clinical trials that state that you will get better care if you enroll on a study.
  - One investigator is the PI of too many studies.
  - Poor departmental records regarding research. Confirm accessibility. Confirm transparency.
  - Any patient complaint that they feel bullied (it happens more than you think).
  - Investigators do not know the protocols and cannot discuss them.
  - No recorded follow-up of post-audit action items.
  - Informed consent process is too quick...should take an hour (or more) if done well.

Efficient Research Participant Billing Processes and Oversight are a Must

- From the standpoint of optimizing process, it is vital to spend time early on to plan for potentially challenging billing issues.
  - Oversight, tools, IT, and dedicated personnel at each step in the process continuum are essential.
  - Organizations dedicate inadequate resources to confirm that this process is efficient and that all dollars are being captured through the billing process.
  - Ensure that there is a mechanism in place to flag visits, suspend charges, review bills, scrub, and then accurately bill payors for routine care AND debit study accounts for non-billable non-standard of care items and services.

Judge the Viability of Making Adjustments to the Clinical Compensation Model

- Many non-academic institutions want to nurture research programs without protecting time for research-related administrative activities to take place.
- The use of an RVU (or similar) model is pervasive. Few of these models accommodate "non-revenue generating" activities like research. Such activities are almost treated like 'hobbies.'
- CFOs and CMOs struggle with how to treat research and/or how to establish a Research RVU.
- In the absence of some accommodation, it is difficult to get physicians to prioritize research.
- Finding ways to measure production when protected time is given is a common component of growing and/or well-run research programs.
- Without, investigators rely on coordinators or others to fulfill their duties thus creating undesirable compliance risk.
Financial Viability
Operational Considerations

Formalize Research Compliance Responsibilities

- Larger institutions need dedicated resources:
  - Research Compliance Officer
  - Research Compliance Work Plan
  - Research Compliance Policies
  - Research Compliance Office

- Smaller, non-academic settings minimally need to have designated specialists within their Compliance functions.

- The landscape (as noted) is complex, fluid, and challenging.
  - Confirm consistency of process, familiarity with expectations, and awareness with laws.
  - Establish training programs.
  - Risk avoidance through compliance initiatives, audits, and monitoring can help organizations save millions in fines, bad publicity, and/or required improvements (i.e., such as those that can promulgated by a Corporate Integrity Agreement, etc.).

Financial Viability
Operational Considerations

Other Target Areas

- Confirm that your research infrastructure is 'right-sized' for your portfolio and that skills are aligned with the unique characteristics of the research that your site is nurturing.

- Look for partnerships and other strategic collaborations.

- Engage in outreach.

- Automate what you can but avoid unnecessary investments in IT.

Research is a specialty and the personnel accountable for its management, oversight, and compliance must have an appreciation for nuance. Dabbling in research is a recipe for disaster.

Summary and Wrap Up
Conclusion and Take Home Message

• Before an institution engages in committing to research, to avoid financial pitfalls:
  - Institutional leaders must develop a strategic plan.
    ▶ Define the long and short-term goals.
    ▶ Establish the type of program desired.
    ▶ Understand your unique strengths, how your site engages in research and what infrastructure exists or should exist to support institutional priorities.
    ▶ Develop a realistic timeline.
  - Create a short and long-term financial plans taking into account indirect ROIs. This is not a short-term investment!
  - Develop a schedule of deliverables for the program AND for individual investigators.
    ▶ Gauge success and provide investigators with institutional expectations.
    ▶ Developing strategies for encouraging more physicians to become involved.

• Put in place appropriate personnel at all levels: executive, IRB, compliance and coordinator.
  - Confirm that all stakeholders, staff and other constituents understand their role.
  - Design audit strategies before research commences.
  - Take into account that operational and financial adjustments may be required along the way as with any new, long-term endeavor.
    ▶ Optimize process.
    ▶ Develop work flow diagrams, tools, job aides, etc.
    ▶ Memorialize expectations in policies and procedures.
    ▶ Invest in communications and training initiatives to confirm everyone’s understanding of how research is to be done.
  - Listen to criticism. Embrace it. Plan to do programmatic review at specific time points or when goals are reached (1 yr, # trials, # patients).

Be patient. Research is rewarding for your patients, your institution and for health care. Clinical trials get drugs approved both by FDA and by payers. Everybody can win when research is done in the right setting.

Questions and Discussion