

# Clinical Trials Strategic Plan

FY 2020 - FY2026



Investigate



Collaborate



Participate

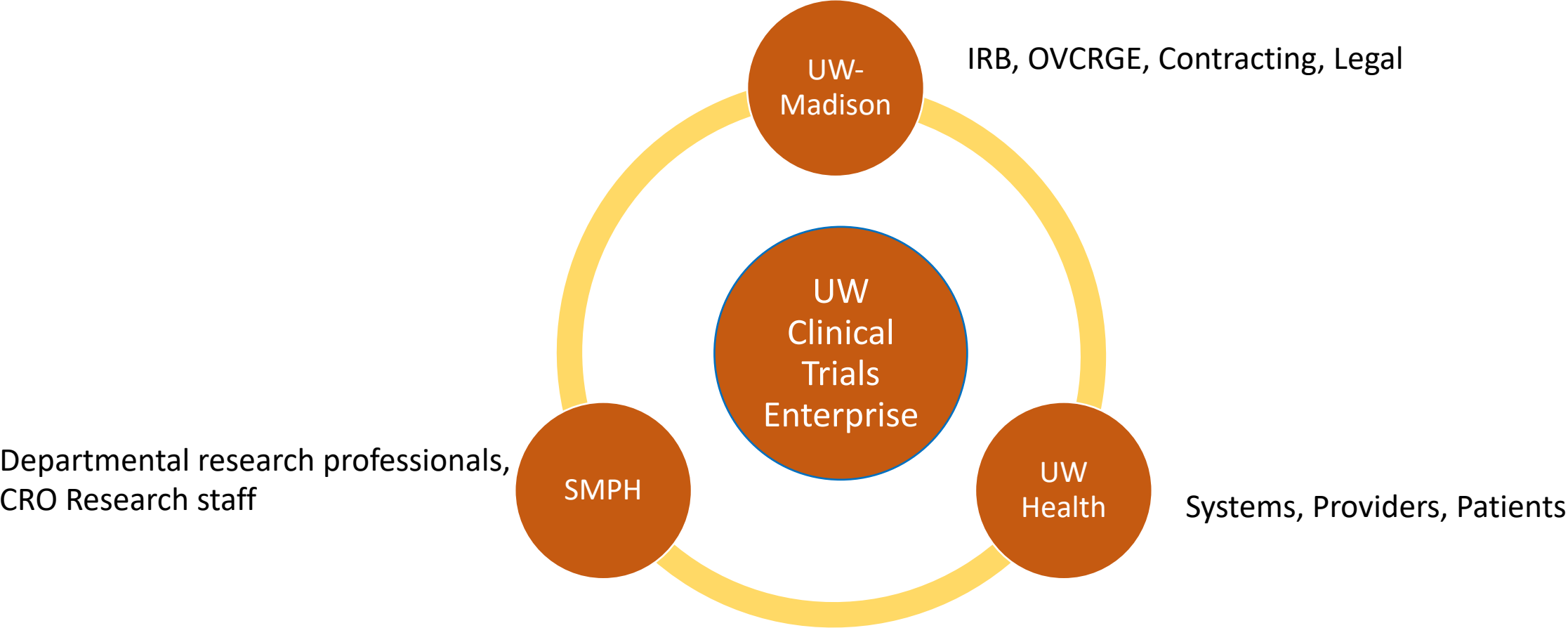
[UWClinicalTrials.org](http://UWClinicalTrials.org)

**UWHealth**



Clinical Trials Institute  
UNIVERSITY OF WISCONSIN-MADISON  
SCHOOL OF MEDICINE AND PUBLIC HEALTH

# Defining UW Clinical Trials



# Clinical Trials is a constantly evolving marketplace



By its very nature, clinical trials is always changing and sites must be able to quickly adapt in order to stay competitive



Start-up companies often have limited cash reserves and need to partner with organizations that understand and meet their needs for quick contracting, activation and enrollment



As the industry moves away from using commercial performance sites, accredited academic health systems will become more desirable



Discovery transfers to industry require clinical trials as part of the process before companies will acquire products



### S Internal Strengths:

- Research staff willing to try new systems
- Commitment of clinical research chairs to be part of process
- Access to highly innovative basic science community
- Collaborations with regional health systems sharing similar processes and identifying patients across the state who are eligible for trials at UW
- Integrated regional health care system linked to SMPH
- Leadership commitment to vision as a premier clinical research organization (UWH and SMPH)
- Consolidated administrative activities can free-up needed research staff resources for growth
- Other strategic initiatives can leverage efficient clinical trials structures

### O External Opportunities:

- Multiple bio-technology firms/CROs in Madison area eager to work with UW
- Established networks interested in participating in multi-center clinical trials with UW
- Numerous long-standing connections with industry partners
- Ability to develop process/relationships to take discovery to clinical trials to patient care
- Highly educated workforce in local areas to recruit as clinical research professionals
- Patient population willing to participate in clinical trials
- Industry expresses value of UW as a research partner
- Contract Research Organizations (CRO) want to identify Key Opinion Leaders (KOL) and interested physician investigators with UW
- Ability to provide clinical collaborations and patient materials necessary to engage the UW community in translational research

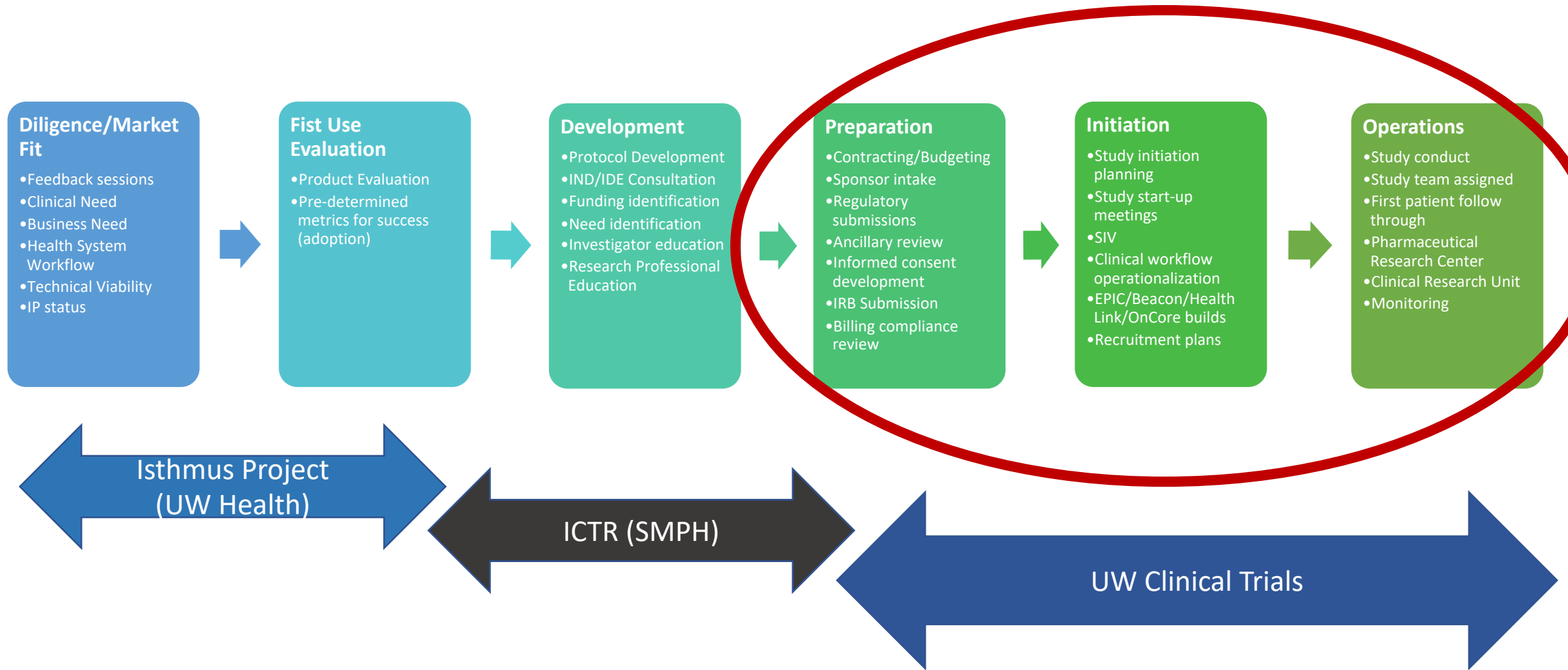
### W Internal Weaknesses:

- Diffuse structure makes having consistent procedures/goals difficult
- Clinical trials contracting and IRB processes are extremely lengthy
- Lack of incentives/goals to encourage industry clinical trial participation
- Patients largely unaware of clinical trials at UW
- Inconsistent training of research staff creates potential risk
- Limited access of research staff to clinical system creates difficulty in clinical trials recruitment and following patients for safety
- Clinical trials mission unclear to clinical staff
- Governance of research activities does not lend itself to enterprise-wide initiatives
- Culture invites work arounds/"middle of the pack" acceptable
- FDA warning letters indicate need for quality process improvements

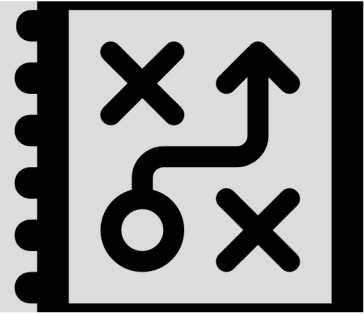
### T External Threats:

- Navigating UW clinical trials systems difficult for sponsors and investigators
- Clinical trials procedure fee schedule most expensive in Midwest area
- Bad press increases the need for UW to reenter the market and be "perfect"
- Industry changes are dynamic and moving quickly, UW needs to be quick to adapt
- Competitors already have streamlined processes and have less expensive fees
- Competition for talent is fierce and costly (informatics, clinical, research), making it difficult to recruit and retain
- FDA can conduct audits at anytime that may require us to work on remedies rather than strategic activities
- Other regional competitor academic institutions will be able to quickly be ACRES accredited

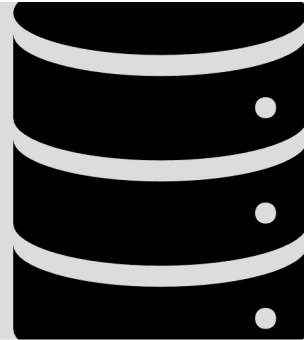
# Innovation and Clinical Research Continuum



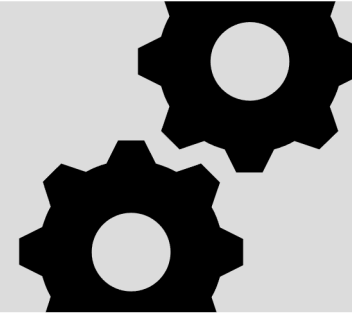
# Clinical Trials Strategies for Success



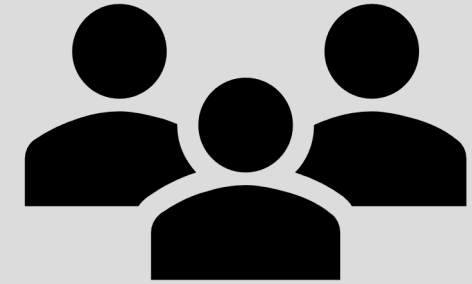
Develop structures to support industry research sponsors and investigators with easier access to clinical trials services



Build systems and processes that support enterprise-wide clinical research today and allow for future growth



Create a quality program that supports clinical research quality and compliance and ACRES Accreditation



Drive culture change by engaging with staff, providers and patients to enhance participation in clinical research

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# Easier access to clinical trials programs

Current processes are difficult for industry partners and investigators to navigate

Strategy

Create single entry point for industry partners and investigators

Related UW Health Goal

Translational Research & Innovation

Key Tactics

**a**

Realign structures by functional areas

**b**

Create sponsor/clinical trials integration team to help sponsors navigate our complex system

**c**

Identify niches and interested investigators and actively market UW Clinical Trials capabilities to industry

**d**

Develop mutually beneficial master service agreements with industry sponsors

Action Items/ Notes

Consolidate similar positions across organization to support larger portfolio and ensure capacity for growth; hire for gaps

Hire specialized and experienced staff to support ease of access externally and coordination/workflow integration across functional areas internally

Clinical trials leadership highly visible to industry; interested investigators/KOLs are listed in site selection databases; site marketing materials

Identify research interests/niches and industry partners sponsoring in those areas; build strong relationships in areas of mutual interest; improve contracting burden



# Common Systems and Processes

Currently multiple and inconsistent processes and systems exist to support research

Strategy

Create standard systems and processes to support clinical research across enterprise

Related UW Health Goal

Translational Research & Innovation, Quality, Information Management

Key Tactics

**a**

Implement consistent training/job descriptions/competencies and recruiting for all research staff

**b**

Identify IT system needs to support clinical research and implement across organization

**c**

Create standard operating procedures (SOPs) for clinical research that are supportive of operations and meet ACRES Standards

**d**

Create capacity to easily move from scientific discovery to clinical trials

Action Items/ Notes

Research coordinator onboarding/training, competency-based career track for all clinical research staff

Create scalable and adaptable systems to support varied locations and types of research

Consolidate and standardize CT SOPs organization-wide; train all research staff on SOPs

Establish partnerships where we need new or additional expertise; develop current programs to be more comprehensive



# Clinical Trials Quality Program

Lack of a clinical trials focused quality program leaves the organization at risk and is a barrier to forming industry partnerships

Strategy

Develop a robust clinical trials quality program to adequately identify risk, support a culture of continuous improvement and work towards ACRES Accreditation

Related UW Health Goal

Translational Research and Innovation, Patient Experience, Quality and Safety

Key Tactics

**a**

Create team to specifically focus on clinical trials quality

**b**

Conduct a risk assessment to guide quality program focus

**c**

Utilize the ACRES standards to provide guidance for developing organization-wide quality initiatives

**d**

Produce regular metrics to monitor clinical trials programs

Action Items/  
Notes

Develop a clinical trials quality team with expertise to drive a culture of continuous quality improvement for processes and systems; resource for all researchers

Understand our highest risk areas and target these for monitoring and process improvement; identify current best practices to be implemented widely

Unique opportunity to utilize ACRES standards to guide the development of our quality program, research processes and systems

Development of standard set of metrics; widely available and current; understand our strengths/opportunities by benchmarking with other institutions

# Culture change around clinical research

Clinical trials are currently viewed as an “add on” activity and not part of the organizational identity

Strategy

Alignment and vision throughout organization of high quality clinical research as part of our shared mission

Related UW Health Goal

Patient Experience, Translational Research & Innovation

Key Tactics

**a** Multi-disciplinary leadership team(s) to guide and support changes to clinical trials infrastructures

**b** Develop and share clinical trials metrics throughout organization

**c** Create communication plan for both UW-SMPH and UW Health

**d** Align incentives around clinical trials goals

Action Items/ Notes

Stakeholder representatives on an Advisory Board and a tactical management team

Internal web-site and metrics to monitor progress toward set goals

Focus on internal and external communications; leadership commitment to clinical research communicated to all staff; patient-centered communication

Develop goals for broad clinical trials teams and incentives for physicians to help drive culture change; use metrics to measure progress

# Collaborative Decision-Making

