

# The Transformational Curve: A Management Tool for Clinical Research Structures

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A new tool to analyze  
resources and to establish  
effective operations



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The Transformational Curve, a new clinical research administration and management tool designed by the Forum on Regulation of the Association of Academic Health Centers (AAHC), provides a guide to establish or improve administrative and management infrastructure for clinical research and to track progress on organizational change. Creating a strong and sustainable infrastructure to support the academic health center research mission, particularly for clinical trials, can ensure effective governance and management, optimize existing institutional resources, and harmonize institutional policies.

This self-assessment tool permits academic health center leaders to (1) track organizational progress in identifying risks and weaknesses in clinical research infrastructure, (2) assess and align organizational strengths, (3) review and analyze organizational resources, and (4) identify the vital elements needed to advance the quality of clinical research and create the optimal state for administrative operations at the institution.

The Transformational Curve assists leaders to analyze processes, procedures, and staffing requirements that support clinical research, specifically clinical trials, and to define the means to change or improve institutional systems. This tool is particularly valuable because it helps institutional leaders review the entire clinical research enterprise and thus avoid the tendency to focus on one segment or function when conducting operational assessments. The Transformational Curve points academic health center leaders to key milestone events in defined operational areas that need to be accomplished to achieve an ideal future state for the institution.

The AAHC Forum on Regulation workgroup on billing and budgeting, which designed the Transformational Curve, agreed that the four foundational pillars of a sound administrative infrastructure were policy, process, people, and technology. Seven agents of institutional change, identified earlier in AAHC studies, were noted as keys to creating the optimal organization structure and a systems-approach to clinical administrative research structure. These are: (1) centralized policy and shared governance (*policy*); (2) consistent and

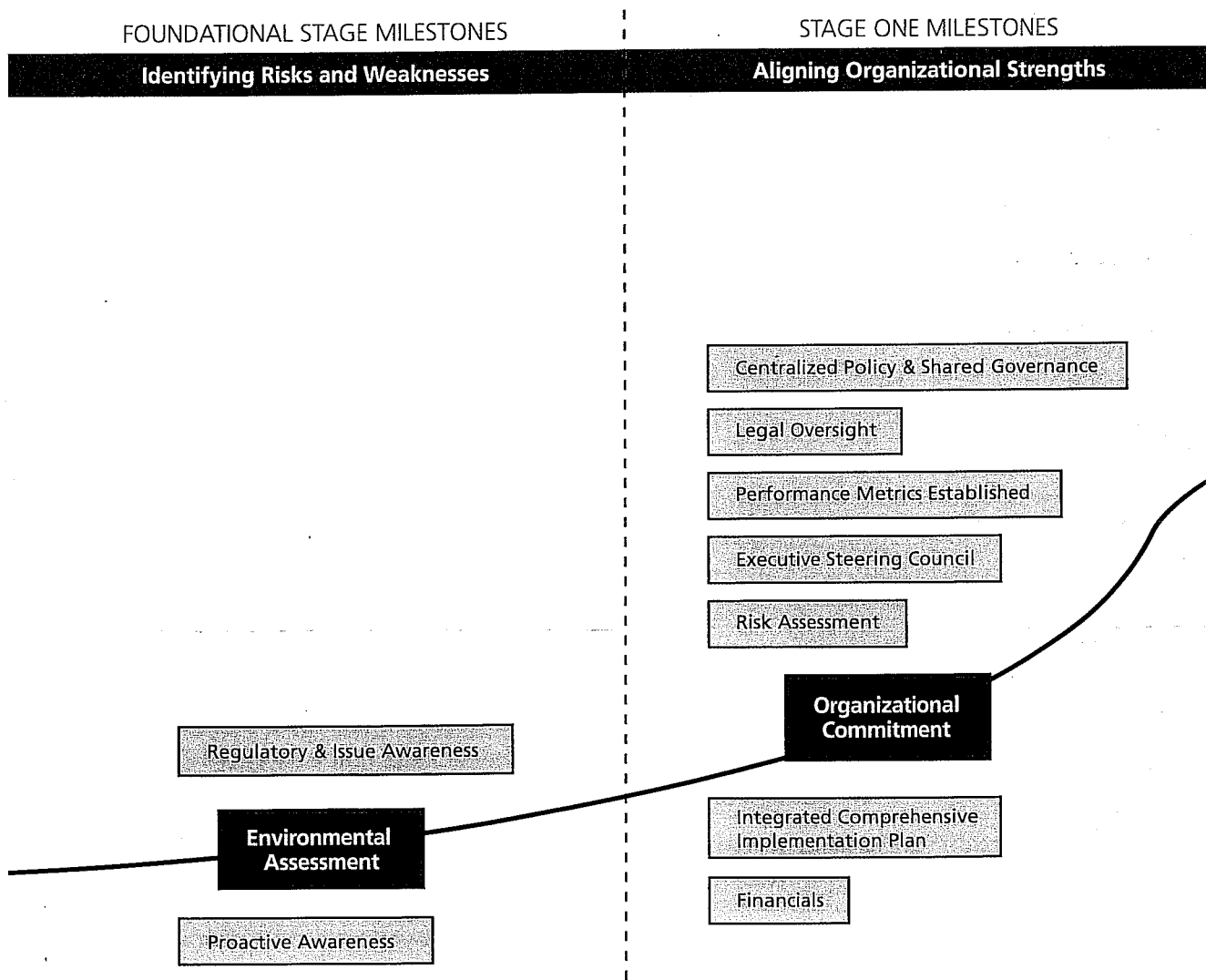
competitive research discounts (*process*); (3) centralized data repository (*process*); (4) auditable management controls and check points (*process*); (5) skill, competency, and productivity assessment (*people*); (6) focused training and education (*people*); and (7) integrated IT solution/industry driven (*technology*).

The seven agents of change were translated into milestone events—that is, core operational events that can shape change. These events were then displayed on the Transformational Curve according to four stages of organizational development—from the least developed (the

foundational stage) to the most advanced (stage three). In each stage, the milestone events build on the events of the previous stage.

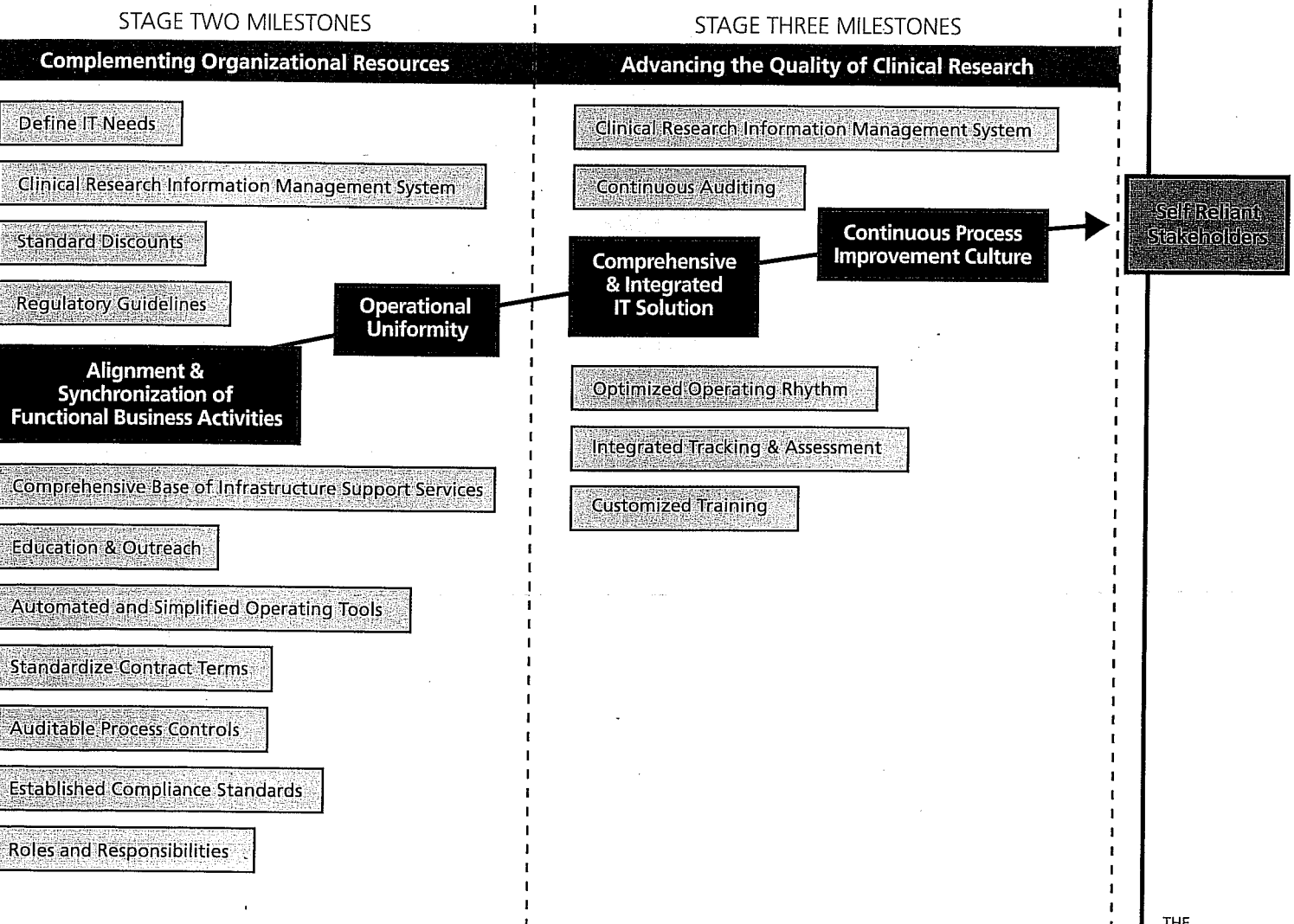
To create a sustainable infrastructure for clinical trials administration, an institution will generally navigate the Transformational Curve by completing all milestone events in one stage before moving on to the next. For example, an institution will usually have a clearly defined financial plan for clinical research or specific research studies before attempting to determine standard research discounts. However, it is possible that institutional leaders have already started to address a number

### The Transformational Curve



of milestones in a later stage of development and have not taken account of events in the beginning stages. In such a case, the Transformational Curve highlights a rationale ordering of processes and permits leaders to address gaps that may be occurring in their system design. In addition, some milestone events, such as the development of training and education programs and IT systems, span all stages of development. However, the scope of activities associated with either the education, training, or IT events would expand with each stage in the process.

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## FOUNDATIONAL STAGE: IDENTIFYING RISKS AND WEAKNESSES

The foundational stage is an awareness stage, the nature of which will vary from institution to institution. While proactive awareness related to the clinical research infrastructure should be a continuous institutional mindset, competing institutional priorities can sometimes distract leaders from giving priority attention to infrastructure. Nevertheless, leaders should not wait until crises emerge. The catalyst for an academic health center to start a change process could be the recognition by administrators of non-workable or dysfunctional elements within the system, or even an external audit.

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The Transformational Curve permits institutional leaders to be proactive by initiating an environmental assessment to identify risks, weaknesses, and gaps in current clinical trials administrative structures and policies. The environmental assessment will give institutional leaders a clear and accurate picture of operations (e.g., number and types of clinical trials, revenues generated, infrastructure costs, staffing and other resources), which is needed before organizational improvement can begin.

The nature and scope of regulatory and compliance awareness within the institution is another milestone event to address. Very often, low staff and faculty awareness of or concern for regulatory and/or compliance issues is a chief barrier to building a solid foundation for process improvement. Upon assessment of regulatory and compliance awareness, institutions may find the need for enterprise-wide communication of institutional policies and practices, which would then lead to outreach, education, and the development of comprehensive staff training programs. At this point, the institution would be ready to move into the next stage of development.

## STAGE ONE: ALIGNING ORGANIZATIONAL STRENGTHS

Milestone events in stage one address issues related to developing centralized policy and ensuring shared governance. Aligning organizational commitment with an effective operational plan of execution is essential. Strong organizational commitment is vital to bringing all stakeholders into the process given that academic health centers consist of numerous entities that often do not share the same priorities. To centralize policy may require that current functions or processes are broken out of traditional silos and re-aligned in a new fashion with a shared vision agreed upon by all stakeholders.

Active hands-on involvement from the top academic health center leaders will be required to ensure meaningful policy and process changes. These leaders must also be involved in the enforcement of policy to sustain change. A key to success in this stage is the creation of an executive steering council, comprising key leaders who represent all stakeholder groups within the institution, to manage the change process and the outgrowth of the environmental assessment. As governance and infrastructure are not always complementary, it is important to establish open lines of communication with all stakeholders to continually educate them about policy changes. Other key milestones to work toward in this early stage of development are:

- Developing an integrated comprehensive implementation plan that details leadership roles and responsibilities;
- Agreeing on the financial philosophy of change and a clearly defined financial plan;
- Establishing performance metrics for assessing, defining, and evaluating policies, systems, and services;
- Establishing mechanisms for evaluation that are built into all structures and processes;
- Ensuring legal oversight that is integrated with compliance, regulatory, research, and clinical offices and functions.

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## STAGE TWO: COMPLEMENTING ORGANIZATIONAL RESOURCES

Stage two permits institutional leaders to review operations and decide where to complement or reallocate existing resources. These milestone events relate to:

- Defining roles and responsibilities of all leadership, staff, and stakeholders;
- Examining relevant regulatory guidelines;
- Delegating responsibilities and determining accountabilities to ensure compliance;
- Defining the IT needs of an institution, with a particular focus on clinical research administration and management and the goal of moving toward automated and simplified operating tools;
- Creating a central repository of clinical research activity information;
- Establishing standardized fee schedules;
- Establishing a comprehensive base of infrastructure support services;
- Establishing compliance standards and monitoring tools; and
- Expanding educational outreach to ensure individualized training, with particular attention to study coordinators and/or principal investigators.

Each milestone will have its own set of tasks and timelines. For example, the first step in creating a comprehensive information system is assessing current tools used to facilitate the flow and sharing of information, asking where information is located and who will need access to information, and determining which tools will need to be updated, replaced, or changed. The AAHC has noted that pertinent information concerning clinical research should be readily available to authorized stakeholders within the institution and data should be managed in a transparent fashion. To get to this future state design will require institutional leaders and technical experts to address data security questions for legal and/or medical records. Other institutions may have financial or IT vendor questions to address.

Delegating responsibilities and accountabilities for compliance will also relate to another milestone that calls for establishing compliance standards and monitoring tools. Institutional leaders should not only ensure that policies are developed, but also implemented with monitoring mechanisms in place. Monitoring and evaluating adherence may require the development of self-assessment

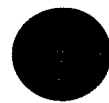
tools for individuals and/or departments or offices. Ultimately, everyone is responsible for ensuring adherence to compliance standards that have been established by the institution.

Institutional leaders will need to assess the base of infrastructure support services to determine the breadth and depth of services necessary to support and ensure compliance across operational areas. Stage two is important because it also shows the interrelationships between milestones. For example, the examination of roles and responsibilities of specific functions and staff will also coordinate with activities that are relevant to establishing a comprehensive base of infrastructure support services.

Auditable process controls, including standardized discounts, are essential to become a high performing organization and should be addressed in this stage of development. Establishing auditable process controls in stage two will eventually lead to continuous internal and external auditing in stage three. Establishing consistent, competitive research discounts that have institutional leadership commitment and are periodically reviewed can also help to establish a tangible partnership for research between the health professions schools and the hospitals.

**“Each milestone will have its own set of tasks and timelines.”**

Institutions should also work toward standardizing contracting terms and agreements to have increased leverage in negotiating contract conditions for clinical trials. To achieve this milestone as well as to enhance budget development and overall clinical research operations, the AAHC Forum on Regulation has recommended that institutions should establish policies for fee schedules and move toward standardized fee schedules for both clinical and professional research services. The lowest common set of fee schedules is necessary for simplicity as well as accuracy. Policies concerning fee schedules should be financially equitable across the academic health center, periodically reviewed, competitively priced, and easily assessable to all staff with authorities and responsibilities related to budgeting and billing. It is essential for institutions to establish simplicity and accuracy in institutional research discounts that both advance and facilitate clinical research and equitably covers institutional



“Educational programs should foster... a culture of accountability.”

costs. This is a critical milestone that will involve numerous stakeholders and will require top leaders to ensure reinforcement in the form of education and awareness as well as enforcement to mitigate any potential policy conflicts that may surface.

Alignment and synchronization of all functions related to the business of clinical research and the subsequent development of a business plan for each of those functions is the essential milestone event that leads to increased uniformity in operations and an ability to move to stage three in the process.

### STAGE THREE: ADVANCING THE QUALITY OF CLINICAL RESEARCH

Stage three brings the institution closer to the ideal state that ultimately will advance the quality of clinical research. This stage addresses the most complex and least developed tools and functions within the academic health center—that is, a comprehensive and integrated IT platform.

The milestone events in this stage are designed to advance the quality of the clinical research enterprise by creating a clinical research administrative and management system that is efficient, automated, auditable, and fully integrated into the research infrastructure. Milestone events include:

- A comprehensive and integrated IT solution for clinical research information management, which must bridge the activities of the university and the hospital, provide operational uniformity and transparency, eliminate manual dependencies, and include an integrated system for budget information and tracking studies and patient visits. Leaders will need to define the parameters of the management system, including the point person or office to administer and manage the system and address the access to and security of data. This will also require establishing a centralized data repository with data on the costs, resources, volume, sources, and impact of clinical trials. Creating a single source of information will serve as an enabling “X” factor, focusing dialogue on both the business and clinical merit of the clinical research enterprise;

- Education, training, and mentoring programs that address all phases of compliance, the significance of institutional policies, the risks of non-compliance, and the various control and evaluation points that are built into the system for all institutional stakeholders. Frequent skill, competency, and productivity assessment for all stakeholders is necessary to effectively align all who participate within the clinical research enterprise with the necessary practical skills that optimize operational performance. Such training should be designed to adapt to changing regulatory, business, and personnel requirements and to account for the need to retain a wide range of personnel by providing career ladders and innovative programs. Educational programs should foster a program of sustainability and a culture of accountability;
- Continuous auditing with auditable management controls and check-points that are: (1) directed particularly at high-risk areas to minimize institutional vulnerabilities; (2) practical across the continuum of activities; (3) comprehensively designed (from research design concept to study close out); and (4) focused simultaneously on compliance, efficiency, facilitation, and continuous process improvement;
- Job areas and skill sets that are well established with required training programs;
- Optimized operating rhythms—that is, cycle times for various processes in the clinical trial life-cycle that improve institutional performance and effectiveness; and
- Ongoing system improvement and evaluation that leads to continuous process improvement and a culture of self-reliant stakeholders vested in and committed to such improvement.

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## CONCLUSION

In today's rapidly changing environment, academic health centers must constantly reinvent and retool themselves based on lessons learned. The Transformational Curve is a valuable assessment tool for academic health center leaders to address clinical research infrastructure. Regardless of institutional size, the scope of current research, established structures, or style of governance, the Transformational Curve provides a means to review the current landscape of processes, systems, and personnel involved in clinical research, assess the need for change, benchmark improvement, analyze resources, and mark progress to a future state that is defined by the institution. This tool highlights inclusiveness for all stakeholders within the institution, attention to individual stakeholder needs, and program integration and sustainability. Most important, the final outcome—the development of an improved future state for clinical research—is based on a culture of accountability that will benefit the institution and the public.

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