



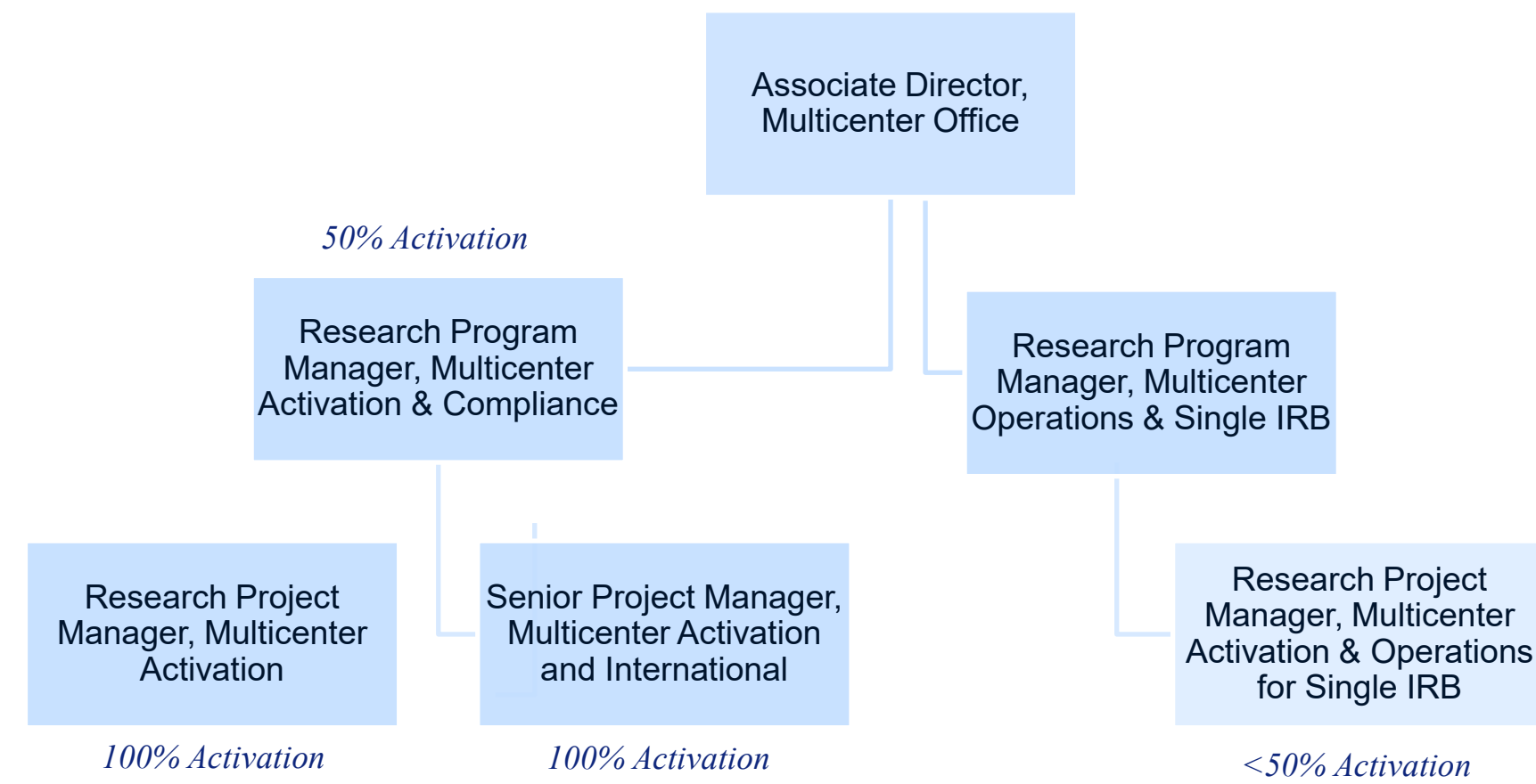
Enhanced Activation of Multicenter Investigator- Initiated Trials with Dedicated Multicenter Activation Team

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Background

MSK Multicenter (MCT) Office is a centralized team dedicated to multicenter investigator-initiated trials (IIT) where MSK is the sponsor and/or data coordinating center. MCT is comprised of three specialized teams: Activation, Compliance, Protocol Operations.



•All MSK protocols are activated by the **MSK Protocol Activation Core (PAC)**, regardless of sponsor and protocol type.

•To **open a multicenter IIT** at MSK, a prime contract with the funder(s) is executed, IRB approval must be granted, and FDA Study May Proceed letter is received, before the participating site activation may begin. This is necessary to provide an external site a complete protocol packet with an informed consent template and sub-contract and budget.

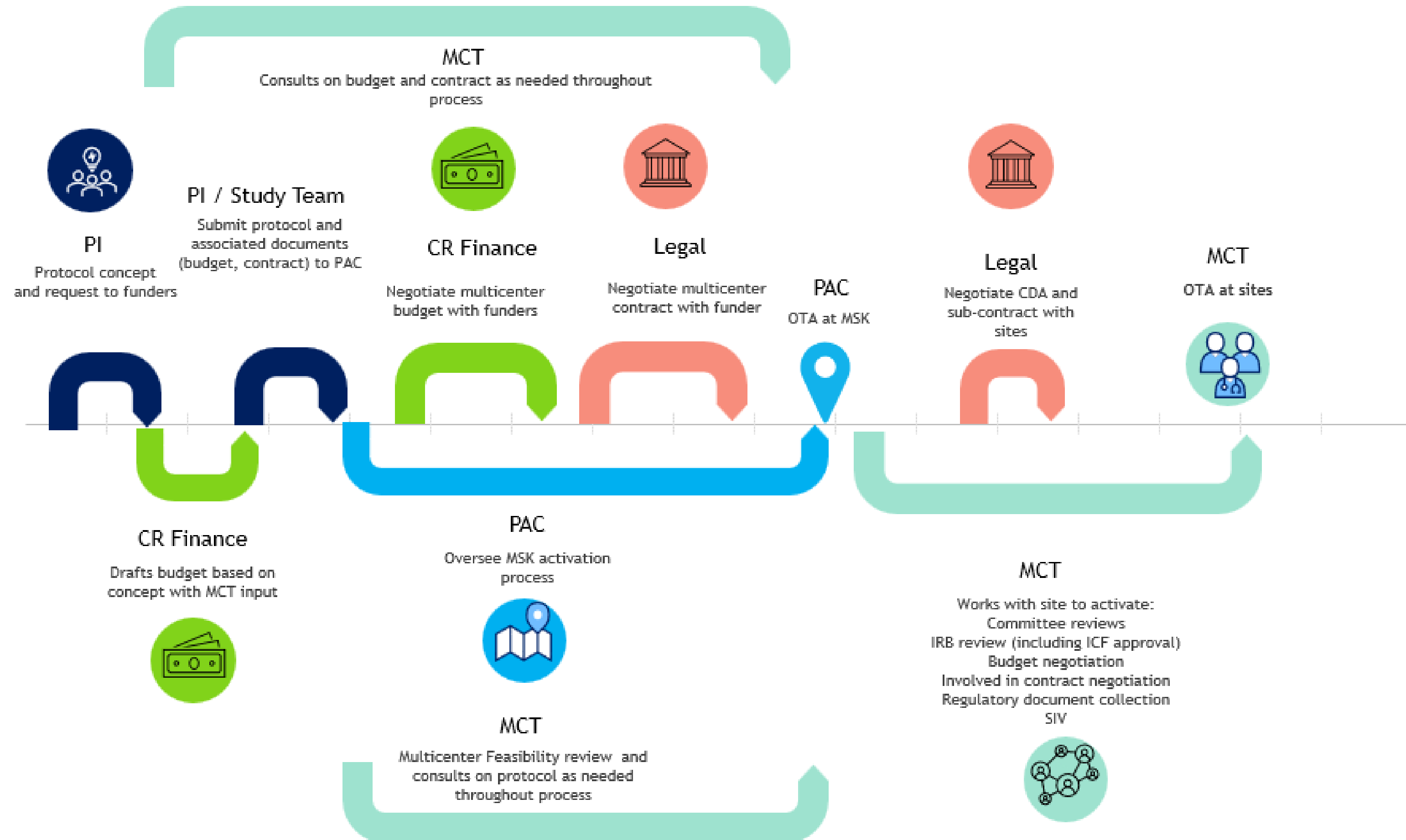
Goals

Ensure **feasibility** of protocols as multicenter studies

Ensure MCT Activation involvement does not adversely affect **time to activation** for MSK

Provide MCT **feedback** during MSK activation to ensure participating site activation initiates once MSK is OTA

Collaborate seamlessly with PAC



Outcomes

MCT Activation involvement **earlier in the process** does not impact ability to activate at MSK and aims to reduce protocol and contract amendments required to initiate external site activation.

In 2024, MCT Office activated **23 sites on 12 studies**. In 2025 YTD (cutoff 5/7/25) MCT Office activated **19 sites on 11 studies**.

This **minimizes** the participating sites' need to submit **protocol amendments** to their local IRBs during their own activation process. In addition, **contract amendments** are reduced by incorporating known site requirements during MSK negotiation of prime agreement(s).

Solutions and Methods

Budgets:

- MCT works with a Clinical Research Budget Manger aligned to multicenter IIT budgets. When asked to work on budget drafts pre-PAC submission, MCT Activation is included and provides input early on.

Legal:

- MCT Activation collaborates with MSK's Legal team to ensure contract terms in prime agreement(s) with funders would be acceptable to participating sites in sub-contracts and align with multicenter operational and regulatory requirements.

Staff Assignment:

- MCT Activation staff members are assigned to studies during MSK activation to ensure expertise in the protocol. During MSK activation, these staff complete multicenter feasibility reviews in parallel to institutional committee reviews.
- Complexity, disease area, and trial type are considered for staff assignments. Expertise and specialization in international collaborations and relying site management guide staff involvement.

Lessons Learned and Future Directions

- MCT should be looped in as **early in the process** as possible when the PI is drafting the initial concept and submitting to funders.
- Integration** of MCT in the PAC processes and collaboration with various MSK teams involved in the activation process improves outcomes for MSK as well as participating sites.
- Moving forward, **international** collaborations are a high priority. Involving teams at international sites early in development ensures country specific requirements and solutions are identified and addressed.