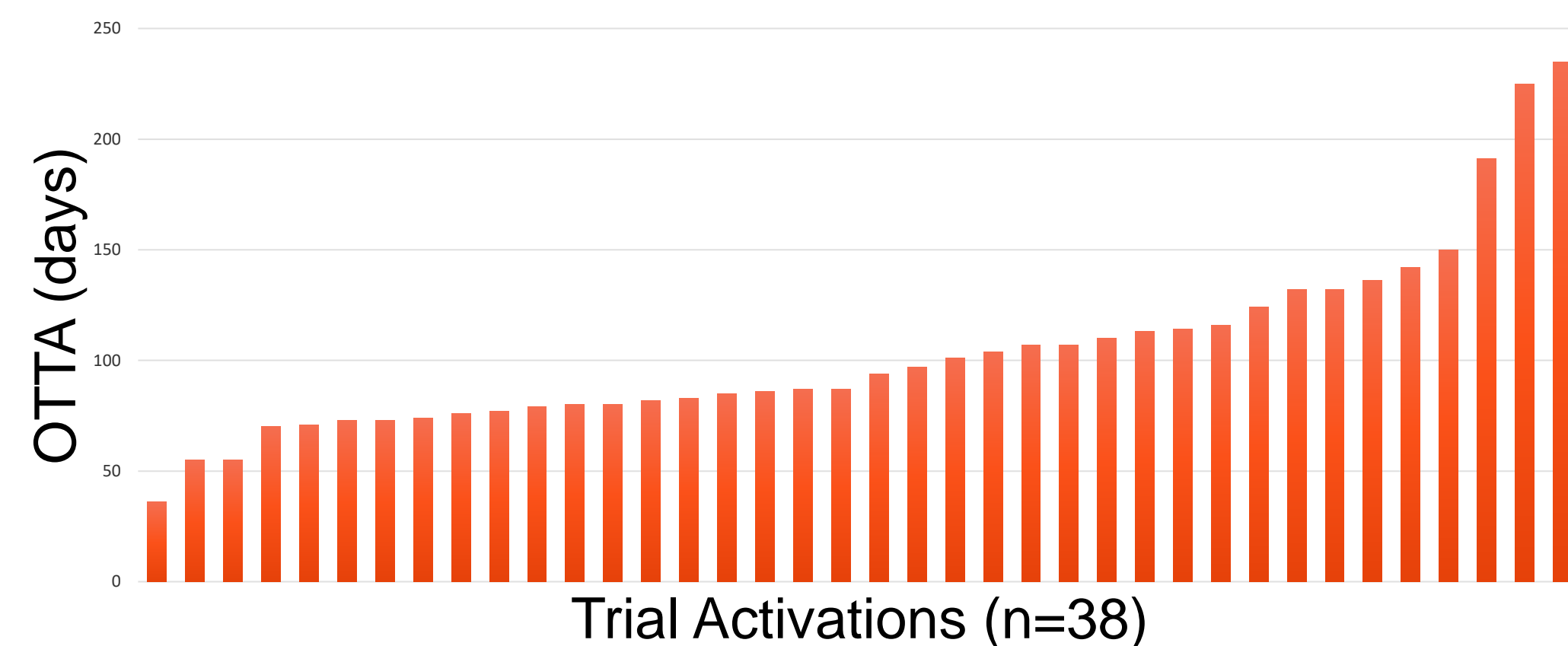




Background

As an NCI-Designated Comprehensive Cancer Center, MSK is committed to collaborations with NCI-sponsored research organizations to increase clinical trial availability. A multistep review process and extensive list of operational items hindered our investigators' ability to provide timely access to new investigational treatments. In 2020, the median overall time to activation (OTTA) was 90.5 days with a maximum of 235 days.

Overall Time to Activation
2020



Methods

Several departments collaborated on a plan to simplify the activation process for NCI-sponsored trials and decrease OTTA, the number of days from acceptance into the Protocol Activation and Review Cores to open to accrual (OTA) date.

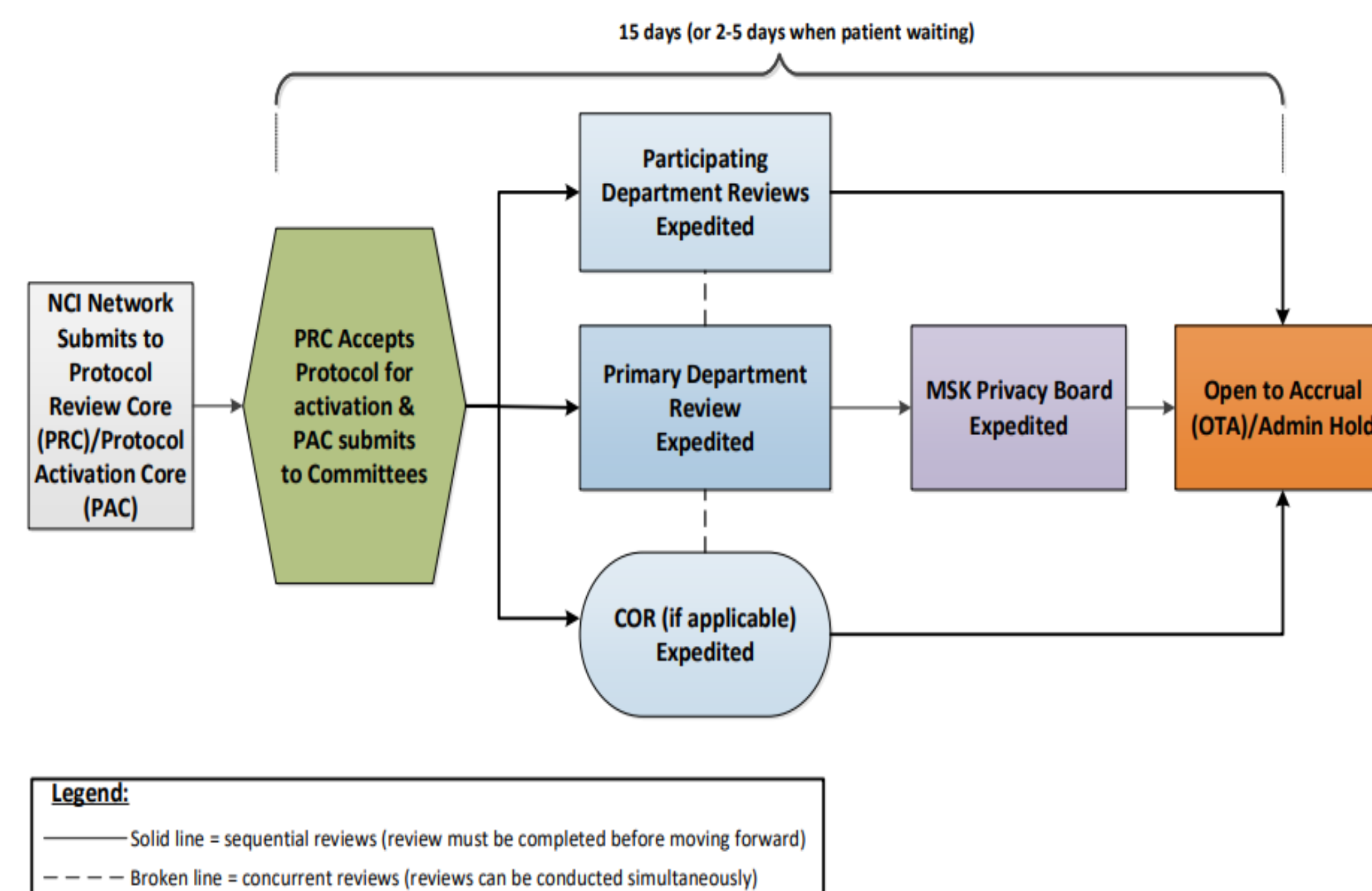
- Identify NCI trial for prioritization
- Determine key operational items required for opening
- Standardize language, decrease # of signatures
- Enable expedited, concurrent reviews

Key Start-up Requirements

We identified five start-up requirements (eligibility checklist, regulatory documents, sponsor activation, initial protocol training, and study-specific contract, if applicable) needed to OTA. The remaining start-up requirements needed to be initiated during the review process and completed within 45 days following OTA (or before the third enrollment).

Expedited, Concurrent Reviews

A streamlined review process allowed for expedited, concurrent reviews. Review time was also cut significantly by using simplified standard language in the Research Proposal Submission Form, eliminating Service Chief sign-off, and ensuring all collaborators adopted the new timeframes.



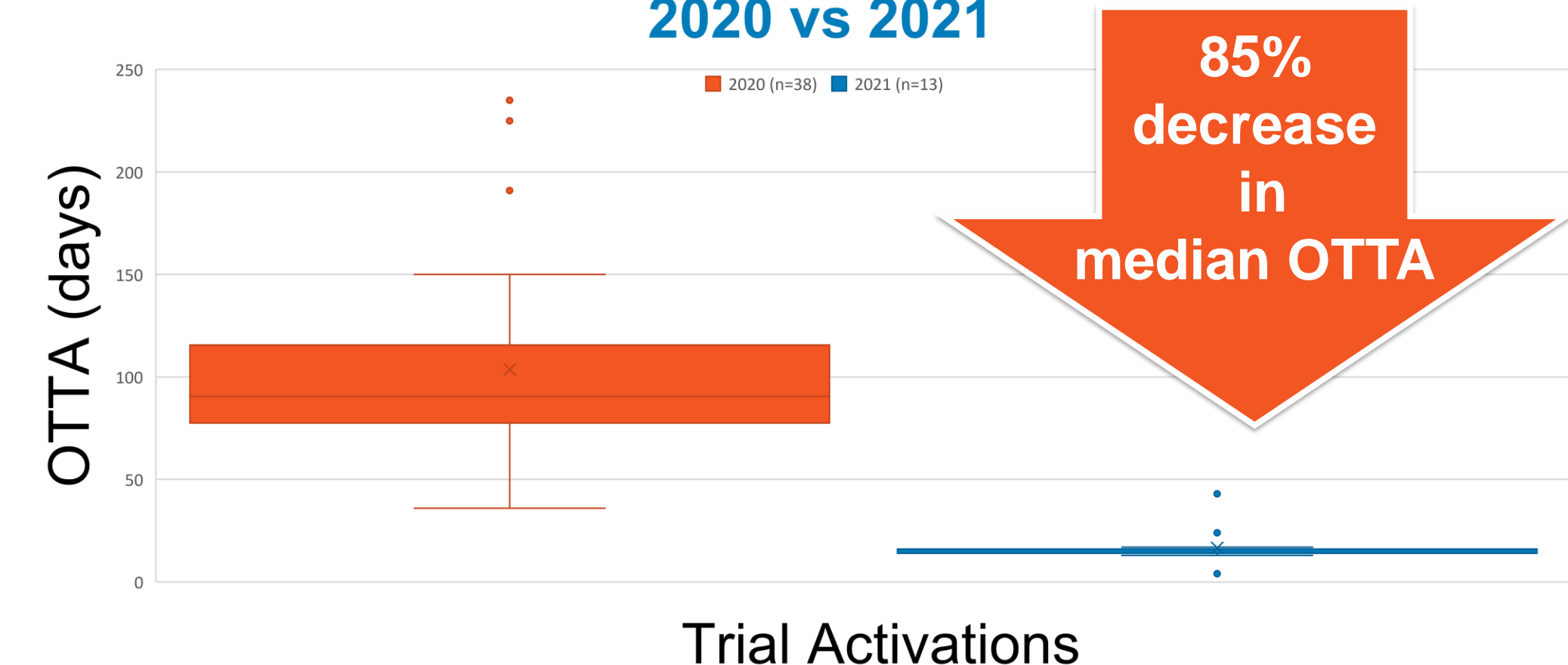
Goals

- Decrease OTTA to 15 days for NCI-sponsored trials
- Pilot Just-in-Time (JIT) model to open trial in 2-5 days

Results

Post roll-out in 2021, we activated 13 trials with a median OTTA of 14 days and a minimum of 4 days for a pediatric trial opened via JIT for an eligible patient. The lesser number of activations was the intended result of a more discerning approach to trial selection. This initiative benefits MSK's patients, giving them access to important research studies, and supports our institutional commitment to NCI-sponsored research.

Overall Time to Activation
2020 vs 2021



Future Plans

- Collect and evaluate 2022 OTTA/ JIT metrics
- Develop workflow to fast-track contract execution
- Expedite Institutional Biosafety Committee reviews

Acknowledgements

Thank you to the following collaborators for their hard work and dedication to making this initiative a success: NCI Network Program, Protocol Activation Core, Protocol Review Core, Local NCI Group Principal Investigators, Human Research Protection Program, Clinical Research Finance, Protocol Operations