*Category: Trial Start-up, Activation, and Protocol Development – Work in Progress*

**Rapid Release Protocol Activation Via a Just-in-Time Pathway**

A. Anderson, T. George, E. Monari, A. Ivey, L. Pettiford

*University of Florida Health Cancer Center*

**1. Background**

To minimize the impact of administrative closures for underperforming rare disease trials, the University of Florida Health Cancer Center (UFHCC) Clinical Research Office initiated the Just-in-Time (JIT) activation process in 2021. The pilot program launched with pediatrics given their relatively large portfolio of rare disease studies. The JIT process was designed in response to the SRMC Zero Tolerance Policy (ZTP), which forces the closure of rare disease studies without enrollment at two years following activation. The ZTP was established in 2018 to force the closure of studies previously allowed to remain open without accrual for several years. To deter closing rare disease studies prematurely, the JIT process allows these trials to conduct all activation activities but remain in a "hold" status until a potential subject is identified, and then immediately activate.

**2. Goals**

- Minimize administrative burden while confirming resource allotment across rare disease portfolios
- Prevent premature ZTP closure of high priority trials expecting slow or limited enrollment
- Activation - ready trials to allow rapid release via the CTMS after subject identification

**3. Solutions and Methods**

The JIT pathway was created for trials that were both 1) NCTN/ETCTN and 2) Rare disease. Initially, the targeted portfolio was pediatrics; however, this was extended to other disease groups.

Qualifying studies proceed through normal activation processes by our UFHCC Protocol Activation Team; upon completing IRB and budget, trials are placed "on hold" until subject identification. All CTMS signoffs are completed except "open to accrual" to limit delays once a subject is ready to enroll. Routine study maintenance *must* continue while in JIT "on hold" status, to ensure that the study immediately proceeds to "open to accrual." This includes study calendar, Beacon builds, IDR release, regulatory updates, training and DTLs.

Once opened to accrual, Data Table 4 (DT4) captures the study along with any enrollments. Disease site group (DSG) meetings include JIT studies to maximize enrollment opportunities. Once enrollment begins, study monitoring and continuation reviews are completed per UFHCC SRMC guidelines. SRMC requires JIT studies to move to "open to accrual" by two years, where studies will follow continuation or termination per the ZTP if no accrual within two years of activation.

**4. Outcomes**

Guidelines were created for activation efficiency, including "Just-in-Time study" must appear in study communications. To date, 13 studies have used JIT pathway, with one study opened to accrual.

DSG portfolios take JIT trials into account as UFHCC limits the number of interventional treatment studies permitted to open. This ensures adequate resources are available since JIT trials may activate at any time.

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**5. Lessons Learned and Future Directions**

The JIT process improved protocol activation communications allowing swift activation for subject enrollment. Analytic review is planned to verify how many studies avoided early SRMC closure due to JIT processes. Modifications may include limits for how many studies a DSG can have a JIT status. Additionally, future plans include enhanced identification of AYA style trials to address required staff and training requirements, as well as gaps in the AYA portfolio for studies that may cross the pediatric/adult clinics.