

MANAGEMENT OF A MULTIDISCIPLINARY PHASE 3 CLINICAL TRIAL IN PATIENTS WITH SYNCHRONOUS MRCC (ADAPT) USING A REGIONAL CHAMPION MODEL IN THE SOCIETY OF UROLOGIC ONCOLOGY–CLINICAL TRIALS CONSORTIUM

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Background: Surgical based multidisciplinary trials pose a unique challenge, particularly for relatively low incidence tumors. We developed a strategy within the SUO–CTC employing Regional Champions (RCs) to overcome potential barriers to timely site initiation and patient recruitment amongst 52 sites participating in the ADAPT trial (Argos Therapeutics). ADAPT is a phase 3 randomized (2:1) study comparing TKI therapy plus dendritic cell immunotherapy (AGS–003) to standard TKI therapy alone in adult patients post CN with clear cell mRCC. This trial required intense coordination involving surgeons, OR staff, pathologists, medical oncologists, leukapheresis and immunotherapy manufacturer. Here, we report novel governance leading to the successful accrual of 712 of 1133 patients enrolled and contributed 273 of 450+ randomized patients over 26 months.

Methods: SUO–CTC developed a RC strategy and identified RCs within 8 U.S. regions paralleling AUA sections. A communication plan was enacted where RC engaged in ongoing site accountability to identify barriers, guide best practices, and update patient accrual. Bi–annual meetings and quarterly conference calls with all investigators were held amongst all study personnel to review trial updates, reassess progress, develop and implement amendments, etc.

Results: Utilizing a prospective RC plan, we demonstrated high rates of trial success at nearly all sites. Of 56 selected sites, 52 (92%) opened the trial (median time 3–9 mo) with 51/52 (98%) sites contributing at least 2 patients to the trial (range: 1–65). The SUO–CTC represented 44% (n=52) of the total number of global sites accruing patients and was able to contribute more than 62% of tumors collected (n=712) and patients (n=273) randomized to study. We identified relative accrual balance across the regions with each contributing an average of 13 patients per site (range 7–18). Despite an amendment, the study completed accrual in 26 months averaging 27.3 patients per month.

Conclusion: Understanding the inherent challenges in a multidisciplinary surgical clinical trial combined with prospective planning enhances overall outcomes in trial conduct and completion. The ongoing engagement of investigators, led by peer to peer communication and RC was a critical success factor to the pace and completion of patient enrollment in this clinical trial, the largest ever, of patients undergoing CN.

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