Case Study:

GLOBAL IMMUNO-ONCOLOGY SUCCESS: PHASE III TRIAL FOR MELANOMA EXCEEDS ENROLLMENT GOALS WITH INNOVATIVE COMBINATION THERAPY

Phase III registrational trial in patients with anti-PD-1 refractory melanoma using an intratumoral study drug in combination with I-O product ipilimumab

480 PATIENTS

100 SITES

11 COUNTRIES

SERVICES PROVIDED

- Project Management and Site Feasibility
- DSMB Management
- Site Activation & Maintenance
- Clinical Monitoring
- Clinical Data Reviews

CHALLENGES

- Protocol V2.0 released one month prior to projected start of enrollment increasing the sample size of the study
- The Sponsor faced sourcing issues for ipilimumab combination product
- Sponsor's Biometrics vendor did not have the experience or capabilities to systemically review and clean the Investigator assessment of response recorded in the eCRFs for RECIST and iRECIST

RESULTS

- Screening began within the original targeted month even with the release of the protocol amendment.
- Even with late release of the protocol amendment, increase in sample size, and delays to central ipilimumab sourcing, Medpace supported the completion of enrollment within 6 months (of the original target).
- The Sponsor acknowledged publicly that the flexibility and global footprint of Medpace supported the successful completion of enrollment even given the challenges to study conduct.

THE SOLUTIONS

- Medpace worked rapidly with the selected study sites to complete amendment submissions with minimal delays to site activation.
- Medpace implemented temporary agreements with sites globally to cover local sourcing and reimbursement processes for ipilimumab to avoid enrollment holds while central sourcing of ipilimumab was implemented.
- Due to timing of the protocol amendment and ipilimumab challenges, additional sites were necessary to complete the enrollment of the study. Medpace rapidly added additional sites in Europe where the current standard of care supported robust enrollment.
- Medpace's Data Review Associates (trained RNs) were added to the study scope to complete systemic reviews of Investigator reported RECIST/iRECIST responses to ensure reported responses followed RECIST/iRECIST guidelines.
    - Cleaned Investigator response assessments were then used in study analysis in comparison to blinded independent review in accordance with the study endpoints.