Tumour as a starting material: Pre-emptive fostering of close working relationships to prevent and address procurement and logistical challenges

The Challenge

Cell therapy studies differ from traditional clinical trials in their complexity, often presenting logistical challenges in respect to the movement of human cells and tissue and the management of couriers and laboratory receipt to align with patient surgical and manufacturing timeslots. The process of procurement needs to be refined to ensure the highest quality tissue and/or blood is collected for the production of an autologous cell therapy product. The successful production and subsequent delivery of this personalised therapy also needs careful alignment with the patient's treatment needs.

Currently the complex infrastructure of the NHS does not always lend itself to the smooth setup and execution of these cell therapy studies, in particular where tumour is used as a starting material. To facilitate smooth and efficient setup of such studies, standardisation of the tumour and whole blood procurement process is required, particularly in the quality of material procured along with refining the logistics associated with sample collection. Additional requirements include the need to build robust patient supply pathways for the patient journey, working with key stakeholders at hospital sites. These relationships need to be established and maintained from early product evaluation in trials and forward for scaled product delivery. Ensuring this will allow such studies to reach more patients, facilitating patient enrolment and support interdepartmental engagement.

The Solution

Ensuring engagement of key stakeholders is crucial for the effective and efficient running of a cell therapy study. Identifying a responsible person at the site who has an overarching understanding of the study and disease area, is able to maintain a steady and collaborative relationship with the Sponsor and has a solid working knowledge of their own site processes and standard operating procedures (SOPs), should be considered. Their ability to form close working relationships with key internal stakeholders (in a cross-functional capacity) is extremely beneficial for the success of the study.

This individual usually has some previous experience of running cell therapy studies and acts as the Clinical Trial Coordinator (CTC) or Clinical Trial Practitioner (CTP) with a support team member who also has experience or has the willingness and enthusiasm to learn over time. In an autologous cell therapy study, the procurement of a patient's tumour (the starting material)

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and whole blood requires a number of supporting departments within the hospital infrastructure to conduct and oversee these activities. Surgeons are required for the procurement of tumour tissue and possibly whole blood with input from allied departments for the oversight of tumour tissue procurement to work alongside surgeons to procure the highest quality sample. . The treating clinician who is normally assigned to the study and acts as the Principal Investigator (PI) will maintain complete oversight of these teams in a trial setting during its early development. The CTCs and CTPs should have direct access to the diaries of all key stakeholders including the research nurse team. Being able to effectively project manage all key groups is essential to the efficient running of the study, and preventing siloed working patterns, which can lead to procurement failures, logistical errors and missed patient identification.

Information on the study should be continually shared by the CTC/CTP among key people, during MDTs or through email. The most efficient method of information sharing for the site should be identified and implemented and may consist of a combination of communication routes. The key to success is the timely sharing of information with the ability to digest and implement recommendations for improvement. This will ultimately facilitate continued improvement in the management of the end-to-end process, from procurement kit handling and shipping, to product delivery. Preparation in advance of the key touch points from a process and personnel perspective will be integral to shared understanding and securing a smooth supply chain for recruited patient.

A central document-housing location, where all key stakeholders can access and review study information and upcoming procurement schedules, should be considered at site. Tracking and maintaining Sponsor feedback in a 'lessons learned' style document is also recommended to support continual process improvement for subsequent procurements. Similarly, sites should provide real-time feedback to the Sponsor following patient recruitment and procurement, including any supply chain issues that were experienced. Two-way, open communication is critical, with the site CTC/CTP at the centre of this and PI maintaining oversight at all times.

The results

By establishing these communication pathways and recommended processes ahead of study initiation, best practices will be ingrained and lead to success with the first patient procurement and beyond.

Making further impact

A best practice guide for cell therapy study start-up and management should be created and shared across NHS sites as educational and supportive material.

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