

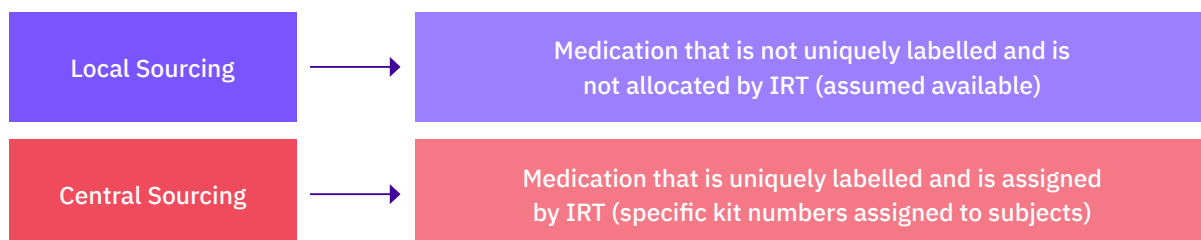
Combining Centrally and Locally Sourced Medication

SITUATION

- Multi-center oncology studies recruit across many countries and may require the management of many different medication types.
- The sourcing of standard of care treatment can be different based on the site location, and may vary from IMP sourcing.
- Sites in one country may need the Interactive Response Technology (IRT) to track and manage stocks of a treatment type, whereas sites in another country may be able to buy sufficient stocks locally.
- When medication is locally sourced, labels do not include a unique kit number that could be used by the IRT to identify the kit.
- In some circumstances, medication sourced locally could be labelled and released into the IRT or, alternatively, the medication could be tracked as a pure “quantity” of non-uniquely labelled kits via dummy kit numbers. These options are not generally utilized however.

CHALLENGE

- Medication requirement checks are made by the IRT at the beginning of medication assignment visits to ensure that suitable medication is available on site for a successful outcome. If medication is sourced locally and not tracked in the IRT, it should not be included in checks.
- The sourcing of a kit type may change during a long trial. Without a flexible IRT, automatic checks will not allow medication dispensing and the patient’s visit will fail.
- Inappropriate medication checks can be detrimental to the course of the trial, as they could result in skipped randomization records, in case forcing is allowed.
- A change to medication sourcing will also have an impact on shipments to sites; if not managed well, the IRT could resupply sites with kits they do not require.



SOLUTION

Calyx designed an IRT solution that enabled trial supply managers to:

- Toggle between medication checks based on the site's "sourcing status" of each kit type
- Have flexibility for central vs. local sourcing at both the country and medication type levels
- Have the control to switch between central and local sourcing in the IRT
- Select sourcing status, which affects supply schemes as well as the associated medication checks
- Reduce medication wastage through intelligent IRT algorithms which only switch to local sourcing once all kits at site have been used

KEY HIGHLIGHTS

Calyx's IRT solution has the ability to apply both central and local sourcing within the same trial and is:

- Adaptable enough to switch kit type/country from central to local sourcing (and vice versa) during the trial
- Able to reduce medication wastage when switching to local sourcing, by using all remaining kits at site first
- Able to avoid "false" failed randomization or failed supply through intelligent medication checks during dispensing visits

COUNTRY	MEDICATION A	MEDICATION B	MEDICATION C	MEDICATION D	MEDICATION E	CODING
US	Central	Local	Local	Local	Local	CEN_A
Canada	Central	Local	Local	Local	Local	CEN_A
Brazil	Local	Local	Central	Central	Central	CEN_C_D_E
China	Central	Central	Local	Local	Local	CEN_A_B
Russia	Central	Local	Central	Central	Local	CEN_A_C_D

Supply scheme automatically set based on the central sourced stock selected (medications A and B in this case)

Supply scheme identifier coded to reflect sourcing selection

Calyx has designed flexible solutions to adapt to centrally and locally sourced medication and to switch sourcing requirements during the course of a trial. Our statistical designers are experts in trial supply management and can advise you how to reach your sourcing objectives.

Calyx can successfully manage various sourcing strategies, giving trial supply managers the flexibility to adapt treatment sourcing throughout the trial.

Contact hello@calyx.ai to learn how Calyx's expertise in IRT can ensure your trials' success.

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