

Understand & integrate needs and preferences

- ✓ **Start early** - Start patient involvement early enough in drug development so that the elements of the solution are robustly in place (integrated) by Phase III. Plan for up-front investment and processes required if patient involvement flags the need for new endpoints and measures, which are achievable but originally not included.
- ✓ **Understand patient needs, preferences, context, environment and culture** - Adapt accessibility, process, shifts in responsibilities and delegation, data flows, and the like to fit patient needs.
- ✓ **Capture, interpret and integrate feedback** - from those involved (i.e., patients, caregivers and the support system as a whole) at every relevant step of the way.

Accommodate needs to ensure accessibility

- ✓ **Provide choices for patients and carers** - plan to address any issues this exposes in current fixed systems (e.g., inflexible protocol templates, new logistics, and/or new costing approaches, and justifying these to budget holders and governance).
- ✓ **Purposefully engaging with care givers** - in the process, trial and solution delivery (including accompanying technology - design thinking)
- ✓ **Training, education and support** - for all involved and all who will be around patients, which address both successes and failures, taking into consideration cultural and disease stage differences.
- ✓ **Reimbursement considerations** - including insurance implications and out-of-pocket expenses.

Manage change & expectations

- ✓ **Balance and manage expectations** - during innovation, whilst also ensuring importance of stakeholder input and involvement is valued and communicated.
- ✓ **Clear communication** - address environmental impact concerns, hesitation (sample and data security), friction in implementation and awareness levels, differing expectations and benefits in different approaches.
- ✓ **Change management** - manage the culture change needed within an organisation as well as within environments for all others involved (e.g., site feasibility and training, phlebotomy services).