Fortrea

CRO Transition Planning Checklist

Five things to plan for when transitioning CROs – Tick each checkbox as you complete the item.

1 Establish a Transition Governance Model

- ❑ Form a transition committee with sponsor, outgoing CRO, incoming CRO, and key vendors
- ❑ Define roles, responsibilities, expectations and decision-making authority
- ❑ Set up escalation pathways and regular governance meetings
- ❑ Create a realistic timeline with assigned accountabilities

2 Reconcile and Secure Your Data

- ❑ Conduct a full reconciliation of clinical trial data (regulatory documentation, vendor status, clinical and safety databases)
- ❑ Validate completeness and accuracy of all datasets
- ❑ Plan and execute secure data transfer to new CRO systems
- ❑ Maintain audit trails and regulatory compliance documentation

3 Communicate with Sites Early and Often

- ❑ Notify sites of the transition and its impact to them
- ❑ Provide updated contact lists and escalation points
- ❑ Offer training for any new systems or processes
- ❑ Monitor site engagement and address concerns proactively

4 Review Contracts and Regulatory Documentation

- ❑ Update contracts to reflect new roles, timelines, and financial terms
- ❑ Review and revise budgets as needed
- ❑ Notify regulatory authorities of the CRO change
- ❑ Confirm all documentation is compliant and up to date

5 Plan for a Knowledge Transfer Period

- ❑ Schedule joint meetings between outgoing and incoming CRO teams
- ❑ Transfer SOPs, operational insights, and lessons learned
- ❑ Document key trial nuances and historical decisions
- ❑ Ensure continuity of personnel where possible

Tick each checkbox as you complete the item.