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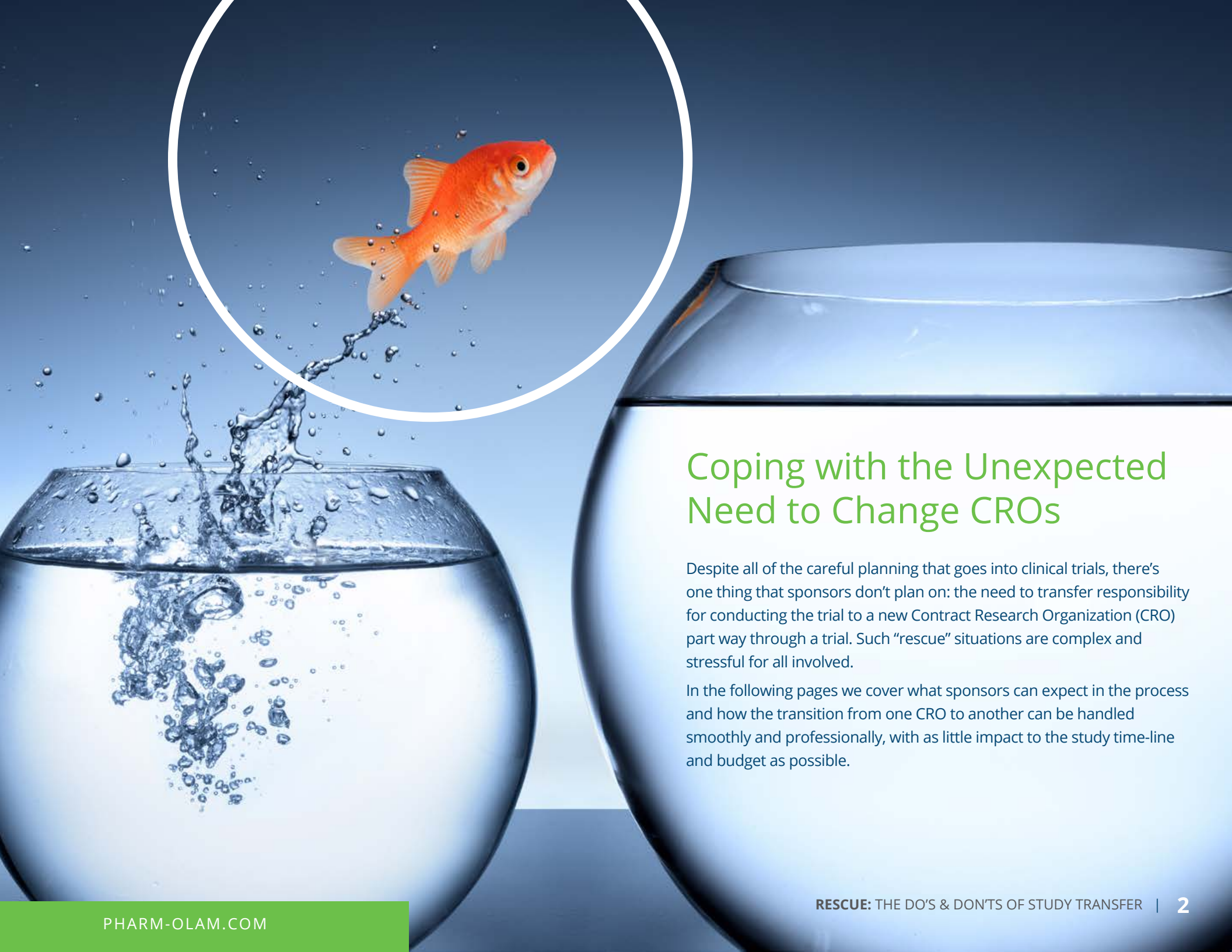
Helping Create A Healthier World

Passing the Baton

The Do's & Don'ts of Study Transfer

An ebook from
Pharm-Olam International
drawn from its webinar series on
Key Clinical Research Topics.



Coping with the Unexpected Need to Change CROs

Despite all of the careful planning that goes into clinical trials, there's one thing that sponsors don't plan on: the need to transfer responsibility for conducting the trial to a new Contract Research Organization (CRO) part way through a trial. Such "rescue" situations are complex and stressful for all involved.

In the following pages we cover what sponsors can expect in the process and how the transition from one CRO to another can be handled smoothly and professionally, with as little impact to the study time-line and budget as possible.

Enter the Process with **Open Eyes**

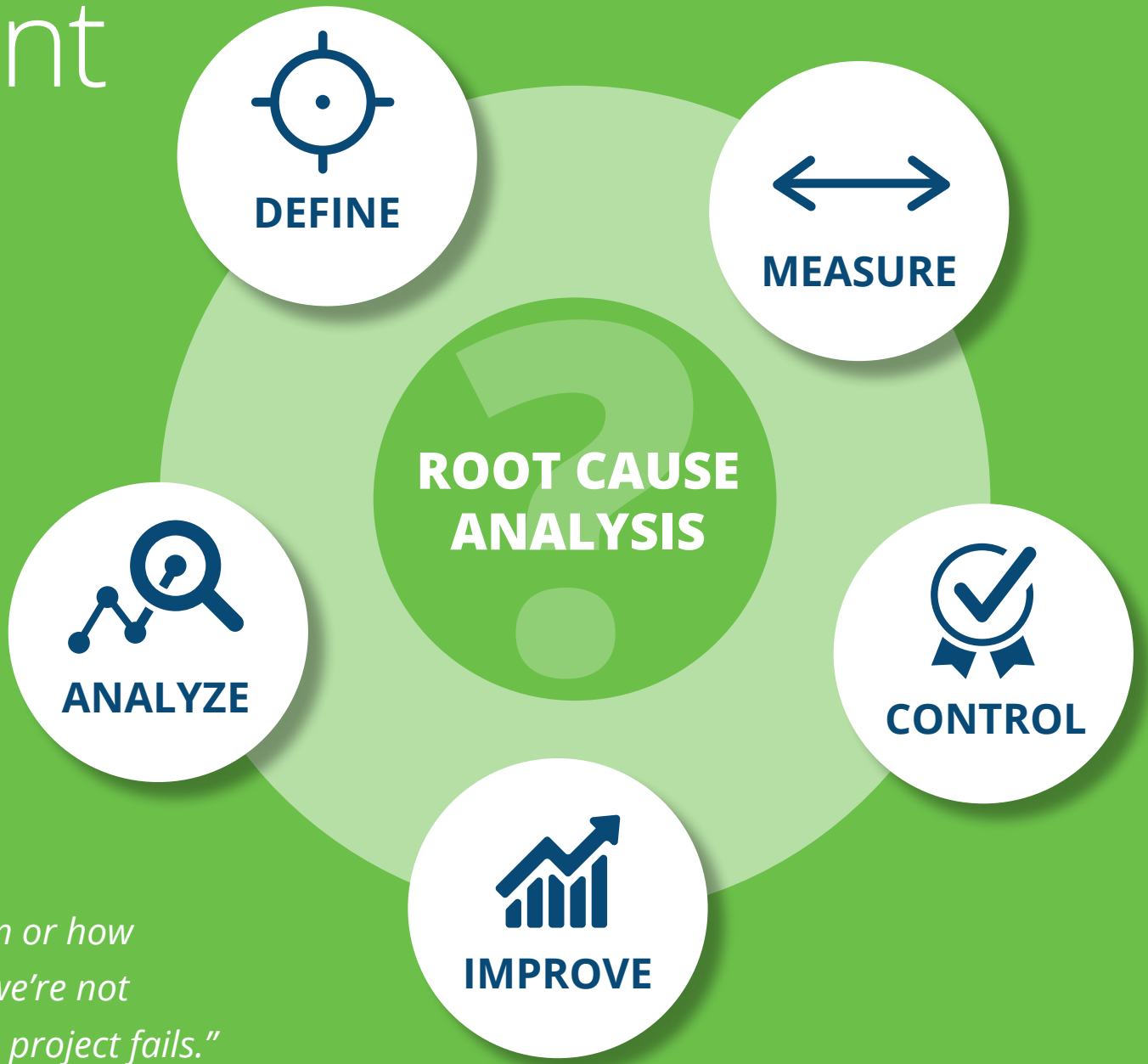
Rescue studies become necessary for many reasons, including performance issues (lagging recruitment, delayed time-lines, poor study management, poor quality data), financial issues and regulatory issues.

A second CRO may be tasked with providing supplemental services, increasing recruitment, or completely taking over the project from the original CRO. This latter situation, while it is the most common, should be undertaken as a last resort. Before taking such a step, sponsors should be fully committed to the process ahead, have support from senior management, and understand that it may take some time to realize the full benefit of the change.

Even in the best of circumstances, transferring a study from one CRO to another will likely be a source of stress and confusion amidst the need to expedite time-lines. The hand-off will require intense sponsor oversight and will almost certainly impact the trial budget.

What Went **Wrong?**

Before you engage a new CRO, it is important to perform a **Root Cause Analysis** to identify the factors that led to the need for the rescue. The degree of difficulty involved in "putting it right" will be tied to the root cause. If the issue is financial (such as the discovery of hidden costs or frequent change orders), the fix might be relatively simple. The same may be true if the problem stems from a lack of resources. On the other hand, if the issue is related to quality (including disappointing enrollment), the situation will require process changes and a very experienced team to get the trial back on track.



"No matter how good the team or how efficient the methodology, if we're not solving the right problem, the project fails."

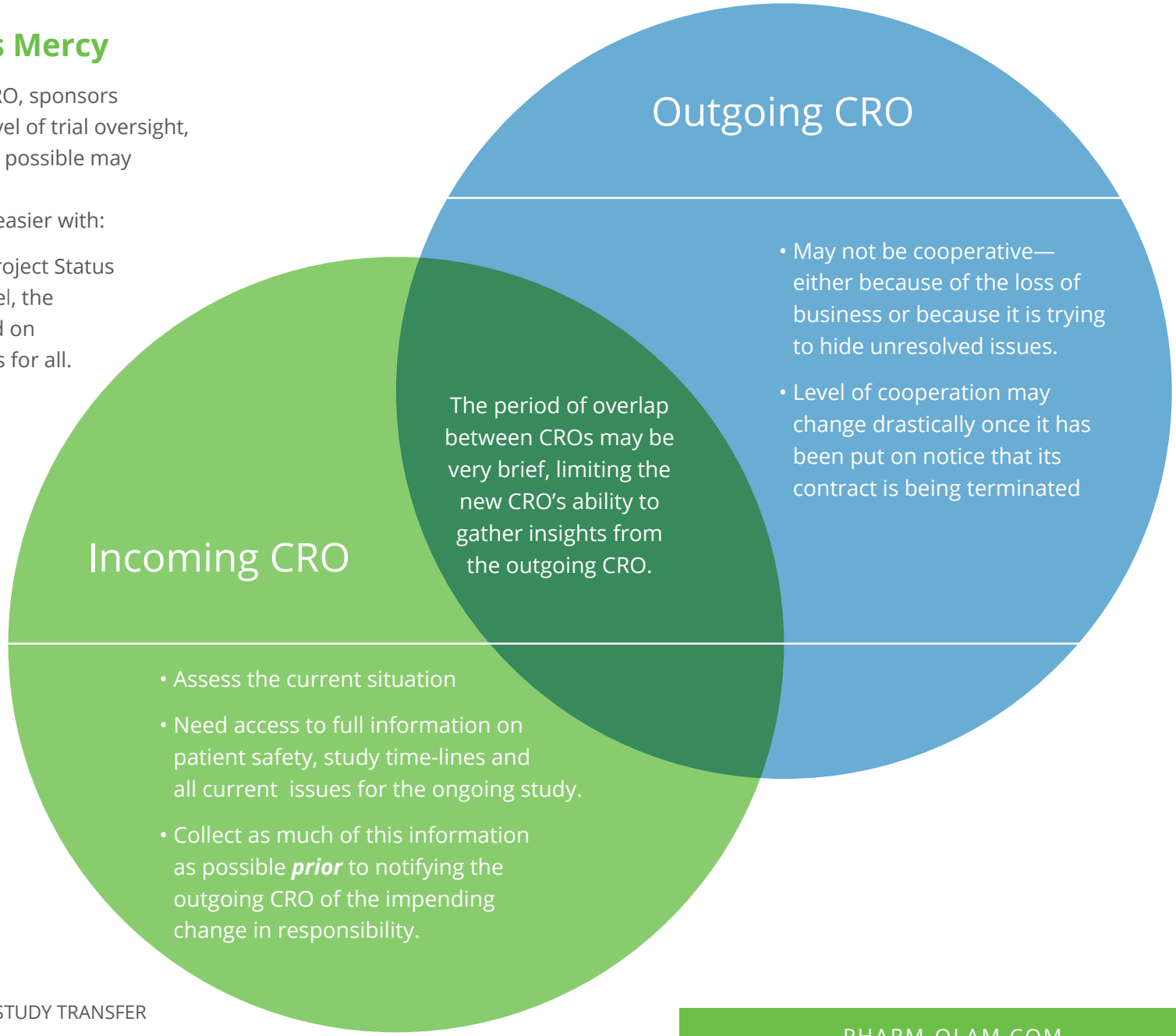
— WOODY WILLIAMS

Assess the Current Status

Don't Be At Your CRO's Mercy

To avoid being held hostage by a CRO, sponsors should always maintain a certain level of trial oversight, although the degree to which this is possible may depend upon the scope of the study, of course. This can be made easier with:

- Proper tracking tools, (i.e. TMFs, Project Status reports, etc.) If this is done via Excel, the spreadsheet should be maintained on a shared drive with anytime-access for all.
- Insist that your CRO send regular, comprehensive status reports. These, too, should be maintained on shared drives.



Develop a **Handover Plan**

Once the new CRO has been briefed, it will be important to create a **Handover Plan** — a document that mimics the final project plan, but limits the scope to the transfer period. Depending on the study, the Handover Plan can be managed by the Sponsor, but we recommend the incoming CRO play a significant role in the design and management of this plan.

While the Handover Plan should be concise, it will typically take a couple of days to prepare.

Elements of a Comprehensive Handover Plan

- Short Historical Overview
- Scope & Specifications
- Current Study Status and Time-lines
- Documentation Overview & Quality Control Plan
- Project Team, including Vendors
- Communication and reporting
- Project Risks
- Migration of Databases
- Hand-Over Actions

Follow a Well-Orchestrated Communication Plan

The timing and content of communication surrounding the termination of the first CRO and the on boarding of the second CRO needs to be carefully coordinated.

As mentioned, it is best to do as much preparation as possible prior to triggering the termination notification. Once the outgoing CRO has been notified, it's in everyone's best interest to move quickly. The sponsor cannot, for financial reasons, afford to let the overlap drag out, the outgoing CRO will be eager to extricate itself, and the incoming CRO will be just as eager to get started. The overlap period should be sufficient, however, to allow the sponsor to communicate the change to third parties and for the new CRO to gather all of the necessary information about the status of the study as well as to reconcile study documents, contracts, and payments.

The outgoing CRO should provide all needed information (as outlined in the Handover Plan) in writing. The sponsor should also moderate teleconferences between the two CROs to answer questions and provide clarification.

Notify Other Stakeholders

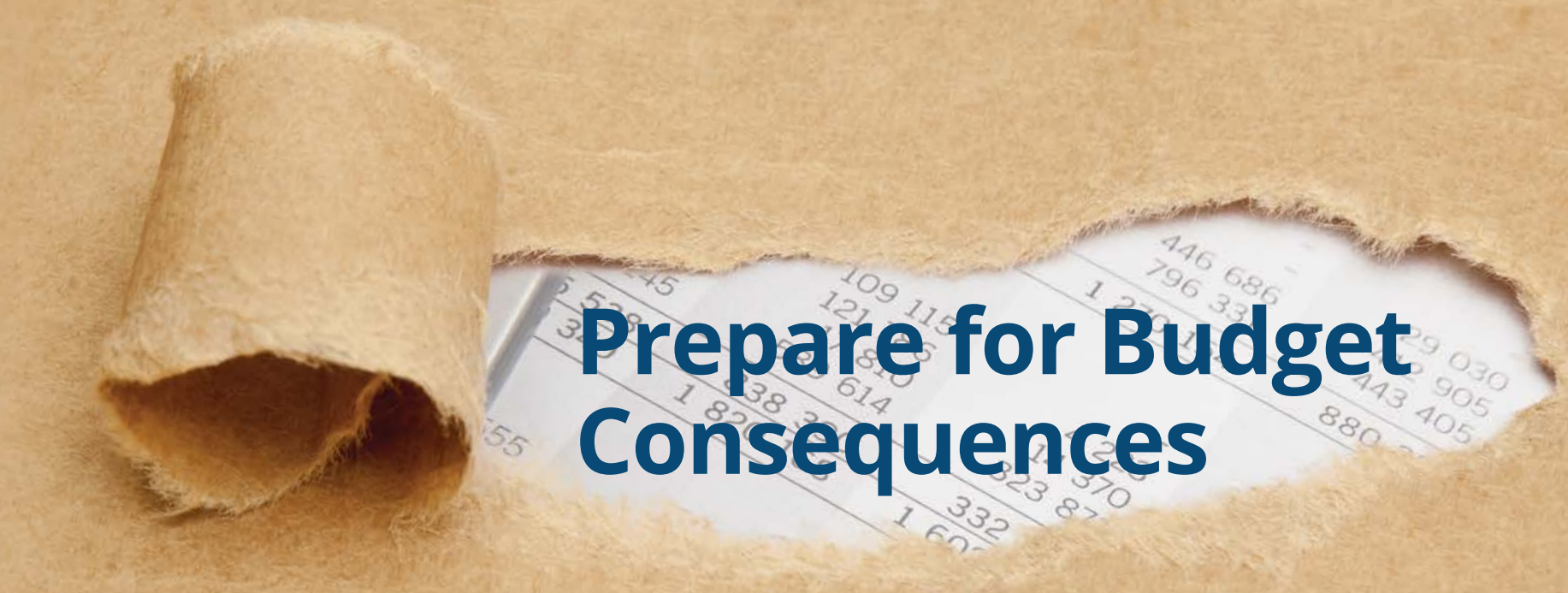
During the transition period — while the outgoing CRO is still engaged — **the sponsor must notify sites, vendors** (i.e. imaging, technology, translation, etc.), **regulatory authorities, and insurers.** In some countries, the authorities must grant approval for the change.

The incoming CRO can then proceed to follow up with sites, giving them a new point of contact. This is important so that sites do not feel abandoned, particularly as the outgoing CRO may no longer be invested in site management. The new CRO cannot yet be expected to be of much support to sites, but at least the relationship will have been established.

If, as is ideal, sites' contracts were with the sponsor, they will be left intact. However, if the contracting party with sites was the outgoing CRO, the new CRO must prepare new contracts for each site. Because it can take some time to establish new contracts with some sites, it is possible to work under a "bridging agreement" confirming that all of the former CRO's obligations with the site will be upheld. This will permit the study to progress as new contract details are worked out.

IMPORTANT NOTE

The two CROs must reconcile all site and vendor payments during the transition period. Sites and vendors, understandably, are reluctant to enter into new contracts with a second CRO until they have been fully paid for their activities to date.



Prepare for Budget Consequences

It is rare — if not unheard of—to be able to hold to the study's original budget once it is in rescue mode and being transferred to a new CRO. The work does not stop on one day with the first CRO and commence on the next day with the new CRO; there is a period of overlap during the transition.

Plus, there are added study management costs associated with the new CRO's:

- Document review
- Assessing status and rectifying mistakes/fixing issues
- Payment reconciliation
- New contract negotiations (if applicable)
- Budget review and revision

A best practice is for the new CRO to begin working on the steps within the Handover Plan based on a Letter of Intent and an agreement on some initial, expected costs. The new CRO will be unable to prepare an accurate comprehensive budget until after it has conducted due diligence.

Demand a Top-Notch Team

Given that the study has needed rescuing, the new team members assigned to it should be extremely well qualified.

They should be:

- Led by expert project managers and versed in change management processes
- Capable of working under great time and workload pressure
- Experienced in the indication, accustomed to the scope of the study, and/or familiar with the regions of the world where the study is being performed
- Located in time zones convenient for the sponsor and/or the outgoing CRO. This will facilitate the information exchange between team members.
- Dedicated and flexible

The number of resources assigned should be sufficient to accommodate the time-frame allotted for the study handover, and so extra resources may be needed temporarily. And, the incoming CRO should be providing heavy senior management involvement during the transition.

Be Aware of the Risks

Rescue Study Risks for Sponsors

- Creeping budget. Many factors will affect the budget, such as the stage of the study and the status of the project.
- Time-line extensions due to the assumption of tasks, project kick-offs, site relationships, database updates, etc.

Rescue Study Risks for CROs

- Lack of information/hidden issues
- Incorrect assumptions
- Complicated regulatory notifications
- Time, workload pressure, fast project developments
- Unfamiliarity with vendors/locations
- Complicated/inefficient inherited project structure
- High sponsor expectations

Typically, sponsors expect that once the new CRO is on board, things will change for the better quickly and effectively. Since there are many factors affecting the successful handover, sponsors should remain patient and cooperative, making themselves available to the new CRO.

Success Factors

For the Transition To Be Successful, Sponsors Will Need To:

- Be prepared to make the handover, having gathered all details on study status from the outgoing CRO
- Handle the announcement of the change carefully, at the right time, considerate of all the sensitivities involved.
- Enlist the ongoing support of the outgoing CRO through the transition process
- Support communications with sites and vendors during the handover phase.
- Provide close project oversight during the transition and be available to the new CRO.

The New CRO has the Responsibility To:

- Quickly and effectively identify the reasons for poor performance in the study and prepare an action plan to rectify them.
- Create and document a rescue process
- Assign an experienced, dedicated, and flexible team
- Ensure effective communication between all parties
- Employ a site management plan to ensure that recruitment goals and study time-lines are met.

As with all change initiatives and complex projects, success hinges on communication. Following a comprehensive communication plan and practicing open and frequent communication between all parties throughout the transition will minimize disruption, reduce the associated stress, and pave the way for optimal results.

A Final Word

With realistic expectations, proper planning, and open communication, the transition process can go smoothly.

See our Webinar: The Do's and Don'ts of Study Transfer »

For more information about Pharm-Olam's experience and its approach to rescuing trials, please contact us at info@pharm-olam.com or visit www.pharm-olam.com.

"Change is not made without inconvenience, even from worse to better."

— Samuel Johnson