TriTiCon

Oversight of Biometrics activities – Three basic steps and two key considerations

About this document

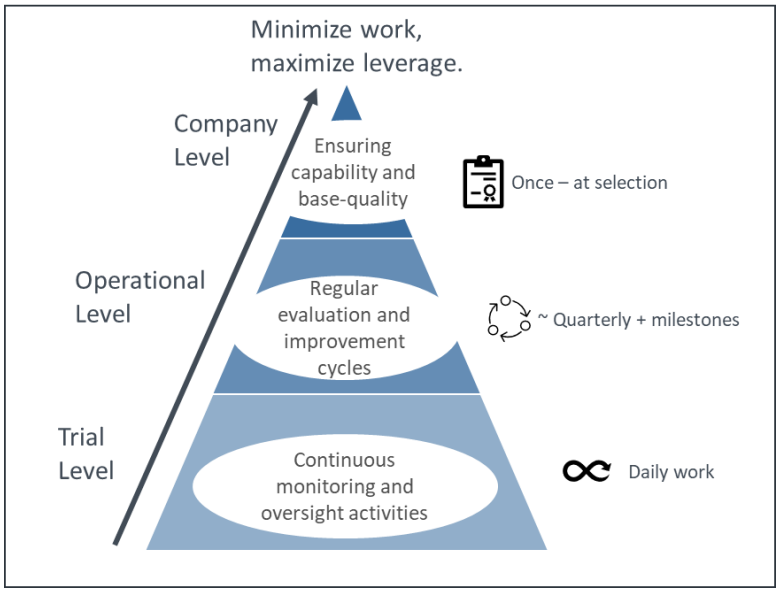
This document is part of TriTiCon's public tools and checklists and is free to use, copy or reference. Contact us for feedback or further information.

Related documents: *Data and Outputs Delivery Checklist, Clinical Standards Overview.*

1 Step 1: Structure - Push activities up the pyramid to minimize work and maximize effect

Organizing oversight activities in the right "levels" helps drive both efficiency and effect. The basic principle is that the higher in the pyramid you go, the less time you use in the long run, whilst also maximizing the effect. There is a win-win in this upfront investment, and it also makes each activity simpler and more efficient if you categorize them in the different levels, with different objectives and outcome.

On the *company – do once – level*, you want to ensure the very key things from a capability and quality perspective. Basically, if these things are not in place, you are not going to work with the vendor. Once they are in place, you are set. The *operational – do regularly – level* is your continuous improvement and escalation point. This is where you consolidate results from trial level activities and take action as required; fact-based and improvement-oriented. Finally, the *trial – daily work – level*, is the continuous activities you do as part of your daily work. These activities should keep things on track and be your "finger on the pulse", but also generate input for the operational level.



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2 Step 2: Content - The why, when, how and what

So, what do we put into these categories – or levels – of oversight activities? Here is our 2 cents:

2.1 Company-level

The selection process - RFI and RFP, references, qualification visits and audits etc – is probably the most important oversight you will ever do. This is where you ensure the basic capabilities (QMS, people and competences, culture, processes and SOPs, systems, and validation), all the things you want from your vendor, i.e., your requirements for the services, including the quality and compliance aspects.

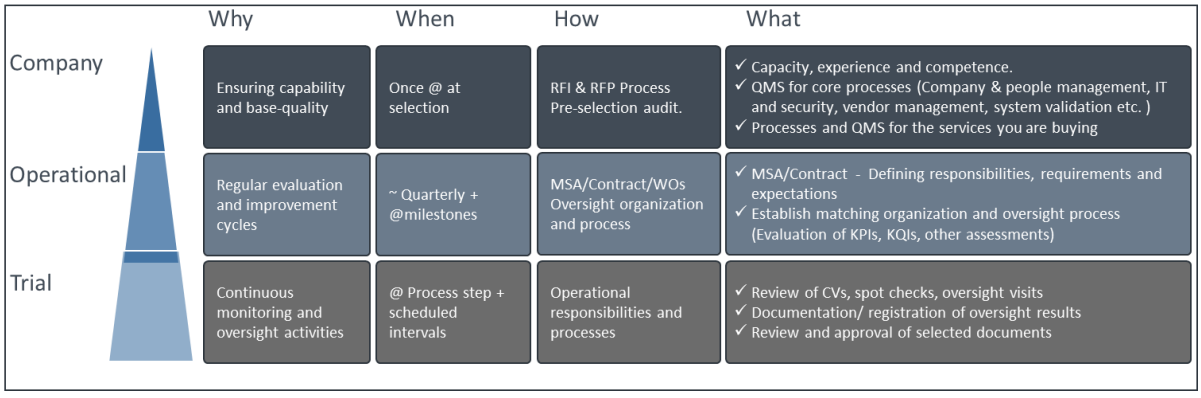
2.2 Operational level

1) **Contracting and agreements**. Setting expectations is key, if we have not defined what we expect, we have nothing to execute oversight against. Setting as much as possible of them in the MSA/Contract, including a standard trial Work Order, gives leverage and decreases the amount of required trial level involvement and oversight i.e., if it is the vendors responsibility to establish data transfers with all vendors on a weekly basis, you do not need to review or approve all plans and specifications on the trial level.

2) **Establish organization and process for oversight** i.e., a joint organization and process with the vendor, with fora for discussion and acting on oversight results and process for collecting oversight results (findings, issues, KPIs and KQIs). Keep it simple but define and keep track of what you measure and who talks to whom about it. Differentiate the trial work and individual "case" from this continuous improvement and make sure you keep it fact-based and holistic (and don't get caught in the subjective and personal).

2.3 Trial level

Here we include things like review and approval of CVs, spot-checks, oversight visits, (yes, for biometric vendors as well), checks on key documents, outputs, and other deliverables. And – last but not least – think, discuss and document quality in daily interactions and meetings. Oversight is not QC (see below), but a QC activity can be used to generate oversight results.



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3 Step 3: Documentation – Plan – do – act, but also document

You must document what you plan to do, what you did and the result. The good news is, that you already did a lot of this; you just need to document it as well. You need to have a SOP describing the overall oversight (if you like what you have read, you can "convert" this document to a SOP) and a Trial Oversight Plan for the trial (based on a pre-populated template) and document the results.

4 At the end

4.1 Oversight is not sponsor QC, sponsor UAT is not end2end testing

Oversight is not QC. It should not be an integrated part of the process nor should it should not be a "check once more to find and correct issues" activity. If we remove the oversight, the outcome should still be the same; we just need to ensure (without intervention) that the outcome is as we want it to be. If not, we correct the process and compensate with more "check-and-correct". I.e., you might QC a SDTM delivery and follow up to have findings corrected. This is not oversight. Tracking, categorizing and assessing the findings, then comparing against expectations, is an oversight activity. These activities should generate facts (KPIs, KQIs (or whatever you want to call them) as well as specific cases for evaluation and action on the operational level: keep this simple but do it and do it consistently. And while I'm at it: Sponsor UAT is not end2end technical testing, but that's another story (coming up soon).

4.2 Risk base

To focus your oversight even more, increase effect, minimize time, and ensure it does what it is supposed to do (i.e., minimize risk), it's recommended to base it all on a simple risk assessment. What are the risks with the sourcing-model, type of vendor and the specific vendor you choose? As discussed in our eClinical Articles (see especially article 3a on system and service selection), you might need to compromise on your wish list and for example choose a vendor with tons of experience in say Rave and Submissions, but less so in the therapeutic area you work in. If so, your oversight of course needs to balance this gap or the risk that it implies for your trial.

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