

REGDESK INTERNAL USE ONLY

Business Case Tools — User Guide

Two tools used together: the **Questionnaire** collects client data; the **Calculator** estimates cost savings. Both follow the same four pillars and the same section order.

TWO-STEP PROCESS

- 1

Complete the Questionnaire with the client (Sections 1–7)
Walk through each section in order. Collect numeric answers. Section 7 (RA Team & Cost Assumptions) must be filled — it drives every calculation in the calculator.
- 2

Transfer answers into the Calculator (Sections 1–7)
Section numbers match between both documents. Enter each value from the questionnaire into the matching section of the calculator, then click **Calculate Savings**

SECTION & PILLAR MAPPING

#	Section Name	Pillar	Questionnaire	Calculator
1	Regulatory Intelligence & Monitoring	PLAN	Section 1	Section 1
2	Standards & Legislation Monitoring	PLAN	Section 2	Section 2
3	Registration Status & Reporting	TRACK	Section 3	Section 3
4	Submissions Management	BUILD	Section 4	Section 4
5	Submissions & Time-to-Market	BUILD	Part of S4	Section 5
6	Technical Documentation & Compliance Forms	BUILD	Section 5	Section 6
7	Change Control & Global Assessments	MAINTAIN	Section 6	Section 7
—	RA Team & Cost Assumptions	PLAN	Section 7	Page 1 inputs

Note: The Questionnaire has 7 sections. The Calculator also has 7 sections but splits Submissions into two (S4 & S5) and places RA Team & Cost on Page 1. All questions and content match.

QUESTIONNAIRE V9 — SECTIONS GROUPED BY PILLAR

PLAN Regulatory intelligence, standards monitoring, and cost assumptions.

Section 1 — Regulatory Intelligence & Monitoring

PLAN

- › Q1. How many people in your RA team perform regulatory monitoring? (# people)
- › Q2. Average hours/week per person on monitoring? (hrs/week)
- › Q3. How many new product launch regulatory plans per year? (plans/yr)
- › Q4. Average hours per new product launch plan? (hours)
- › Q5. How many existing-product-to-new-country regulatory plans per year? (plans/yr)
- › Q6. Average hours per existing-product-to-new-country plan? (hours)

Section 2 — Standards & Legislation Monitoring

PLAN

- › Q7. How many people monitor standards, legislation, and guidances? (# people)
- › Q8. Average hours/week per person on standards monitoring? (hrs/week)
- › Q9. How many standards/legislations change per year requiring formal assessment? (per year)
- › Q10. Average hours per assessment process? (hours)

Section 7 — RA Team & Cost Assumptions

PLAN

- › Q24. Average fully-loaded annual cost of an RA team member? — salary × ~1.3 (USD/year)
- › Q25. Average productive working hours per year per FTE? — typical: 2,000–2,400 (hrs/year)
- › Q26. How many RA employees (full-time)? (# FTEs)
- › Q27. How many RA contractors or consultants? (# FTEs)

TRACK Registration status and reporting.

Section 3 — Registration Status & Reporting

TRACK

- › Q11. How many regulatory status queries/reports per month? (queries/month)
- › Q12. Average hours per report? (hours)

BUILD Submissions, technical documentation, and deliverables.

Section 4 — Submissions Management

BUILD

- › Q13. How many global regulatory submissions per year? (submissions/yr)
- › Q14. Average hours coordinating deliverables per submission? (hours)
- › Q15. Average monthly revenue per product per market? (USD/month)
- › Q16. Estimated months a RIM solution could accelerate time to market? (months)

Section 5 — Technical Documentation & Compliance Forms

BUILD

- › Q17. How many GSPR/EPC created or revised per year? (per year)
- › Q18. Average hours per GSPR/EPC creation/revision? (hours)
- › Q19. How many Declarations of Conformity created or revised per year? (per year)
- › Q20. Average hours per DoC creation/revision? (hours)

MAINTAIN Change control and global assessments.

Section 6 — Change Control & Global Assessments

MAINTAIN

- › Q21. How many change control assessments per year? (assessments/yr)
- › Q22. Average # of countries impacted per change? (countries)

CALCULATOR V3.5 — HOW TO USE

- 1

Page 1 — Client Info & Cost Assumptions (from Questionnaire Section 7)

Fill client name, contact, title, date. Then enter Q24 (FTE cost), Q25 (hrs/year), Q26 (# FTEs), Q27 (# contractors), and avg monthly revenue per market.
- 2

Page 2 — **PLAN** Sections 1 & 2 + **TRACK** Section 3

Section 1 (Q1–Q6): RegIntel monitoring & plans | Section 2 (Q7–Q10): Standards monitoring | Section 3 (Q11–Q12): Registration status reporting
- 3

Page 3 — **BUILD** Sections 4, 5, 6 + **MAINTAIN** Section 7

Section 4 (Q13–Q15): Submissions | Section 5 (Q13, Q15–Q16): Time-to-Market | Section 6 (Q17–Q20): Tech Docs | Section 7 (Q21–Q23): Change Control
- 4

Click Calculate Savings (Page 1 or Page 3)

Runs all formulas. The Savings Summary on Page 1 fills automatically — recoverable savings & FTE equivalents per pillar, plus total projected savings.

BUTTONS

Button	What it does	When to use
▶ Calculate Savings	Runs all formulas, fills Savings Summary	After entering all inputs on pages 2–3
>> Import Client FDF	Loads a previously saved client data file	When re-opening a saved client session
>> Export FDF	Saves all entered values to a .fdf file	To save and share client data
Export Report	Opens a web report with client results	To generate a shareable output

- Always fill Questionnaire Section 7 first — FTE cost and hrs/year are the base for every calculation. Without them all results will be zero.
- Export FDF after every session — saves all entered values so you can reload them next meeting with Import Client FDF.
- Estimates are fine — the questionnaire includes typical ranges (e.g. 2,000–2,400 hrs/year) to guide the conversation when clients don't have exact numbers.