

REGDESK INTERNAL USE ONLY

Business Case Tools — User Guide

This guide covers the two tools used to build a client business case: the **Questionnaire** (collect client data) and the **Calculator** (estimate cost savings). Both are organized by the four RegDesk pillars: PLAN, TRACK, BUILD, and MAINTAIN.

OVERVIEW — TWO-STEP PROCESS

- 1 Complete the Questionnaire with the client**
Walk through sections 1–7 with the client. Each section maps to a RegDesk pillar. Collect all answers as numbers — the questionnaire is a fillable PDF form. Section 7 (RA Team & Cost Assumptions) must be completed last as it drives all calculations.
- 2 Enter answers into the Calculator**
Open the Calculator (separate PDF). Transfer each value from the questionnaire into the matching section. When all inputs are entered, click **Calculate Savings**.
. The Summary on Page 1 auto-fills with recoverable savings per pillar and total projected savings.

PILLAR STRUCTURE — BOTH DOCUMENTS

PLAN Sections 1 & 2 Regulatory Intelligence & Monitoring + Standards & Legislation Monitoring Tracks how much time is spent staying current on regulatory changes.	TRACK Section 3 Registration Status & Reporting Tracks effort spent managing and reporting registration status.
BUILD Sections 4, 5 & 6 Submissions Management + Time-to-Market + Technical Documentation Tracks effort and revenue impact of building submissions and documentation.	MAINTAIN Section 7 (Calculator) / Section 6 (Questionnaire) Change Control & Global Assessments Tracks change control effort across global markets.

QUESTIONNAIRE — SECTION REFERENCE (V9)

Section 1 — Regulatory Intelligence & Monitoring

PLAN

- Q How many people perform regulatory monitoring?
- Q Average hours/week per person on monitoring?
- Q How many new product launch regulatory plans per year?
- Q Average hours per new product launch plan?
- Q How many existing-product-to-new-country regulatory plans per year?
- Q Average hours per existing-product-to-new-country plan?

Section 2 — Standards & Legislation Monitoring

PLAN

- Q How many people monitor standards, legislation, and guidances?
- Q Average hours/week per person on standards monitoring?
- Q How many standards/legislations change per year requiring formal assessment?
- Q Average hours per assessment process?

Section 3 — Registration Status & Reporting

TRACK

- Q How many regulatory status queries/reports per month?
- Q Average hours per report?

Section 4 — Submissions Management

BUILD

- Q How many global regulatory submissions per year?
- Q Average hours coordinating deliverables per submission?
- Q Average monthly revenue per product per market?
- Q Estimated months a RIM solution could accelerate time to market?

Section 5 — Technical Documentation & Compliance Forms

BUILD

- Q How many GSPR/EPC created or revised per year?
- Q Average hours per GSPR/EPC creation/revision?
- Q How many Declarations of Conformity created or revised per year?
- Q Average hours per DoC creation/revision?

Section 6 — Change Control & Global Assessments

MAINTAIN

- Q How many change control assessments per year?
- Q Average # of countries impacted per change?
- Q Average hours per country-level assessment?

Section 7 — RA Team & Cost Assumptions

PLAN

- Q Average fully-loaded annual cost of an RA team member? (salary × ~1.3)
- Q Average productive working hours per year per FTE? (typical: 2,000–2,400)
- Q How many RA employees (full-time)?
- Q How many RA contractors or consultants?

CALCULATOR — HOW TO USE (V3.5)

- Page 1 — Client Information & Cost Assumptions**
Fill in company name, contact, title, and date. Then enter the 5 cost assumption values from Questionnaire Section 7: FTE cost, productive hours/year, # FTEs, # contractors, and average monthly revenue per market.
- Page 2 — PLAN & TRACK inputs**
Enter values for Sections 1–3 from the questionnaire: Regulatory Intelligence (6 inputs), Standards & Legislation Monitoring (4 inputs), Registration Status & Reporting (2 inputs).
- Page 3 — BUILD & MAINTAIN inputs**
Enter values for Sections 4–7: Submissions Management (3 inputs), Submissions & Time-to-Market (3 inputs), Technical Documentation (4 inputs), Change Control (3 inputs).
- Click Calculate Savings**
Available on Page 1 and Page 3. Runs all formulas and fills the Savings Summary table on Page 1 automatically — recoverable savings and FTE equivalents per pillar, plus total projected savings.

CALCULATOR BUTTONS

▶ Calculate Savings

>> Import Client FDF

>> Export FDF

Export Report

Button	What it does	When to use
▶ Calculate Savings	Runs all formulas, fills the Savings Summary on Page 1	After entering all inputs on pages 2–3
>> Import Client FDF	Loads a previously exported client data file (.fdf)	When re-opening a saved client session
>> Export FDF	Saves all form field values to a .fdf file (password protected)	To save client data for later use or sharing
Export Report	Opens a web report with the client's results	To generate a shareable output for the client

TIPS

- Fill Section 7 of the questionnaire first** — the FTE cost and hours/year values are the base for every calculation in the calculator. Without them, all results will be zero.
- Use the questionnaire as a discovery tool** — some clients won't have exact numbers. Reasonable estimates are fine. The questionnaire includes typical unit ranges to help guide the conversation (e.g. 2,000–2,400 hrs/year).
- Export FDF after every session** — this saves all entered values so you can reload them at the next meeting without re-entering everything. Password for export: ask your RegDesk team lead.