CITELINE
REGULATORY

Use Case

No More Swiss Holes: Filling the Gaps in Clinical Trial Disclosure

January 2026

The challenge

A pharmaceutical sponsor is preparing to conduct a Phase I interventional drug trial in Switzerland. While the company has extensive experience running clinical trials in major markets like the US and the EU, this will be its first study in Switzerland.

The disclosure team is uncertain about regulatory requirements specific to Switzerland. It needs to understand whether trial registration is required, what information must be disclosed, when disclosures must be made, and which registry or platform should be used for submissions.

The solution

The team turns to TrialScope Intelligence — a centralized, interactive repository of global clinical trial disclosure regulations and insights — to navigate these unfamiliar requirements. TrialScope Intelligence's library contains over 1,000 authoritative regulatory texts globally, providing source documents in their original language along with English translations.

TrialScope Intelligence maintains 59 registry records globally, each providing detailed technical specifications across more than 86 data fields, including submission workflows, data formats, contact details, and registry-specific processes.

The process

1 STEP 1: Starting with the country profile

In the TrialScope Intelligence platform, the user begins with the country profile for Switzerland, one of 193 country records available globally. This profile includes:

- the governing regulatory bodies and competent authorities responsible for clinical trial oversight
- the general application processes for conducting trials in this jurisdiction
- key disclosure obligations

For Switzerland, the user learns that the Swiss Agency for Therapeutic Products (Swissmedic) and the Federal Office of Public Health (FOPH) serve as the primary regulatory authorities, operating under frameworks such as the Federal Act on Research involving Human Beings (HRA) and the Ordinance on Clinical Trials in Human Research (ClinO). The profile indicates that clinical trial registration is mandatory and legally required, and that specific disclosure obligations exist for certain study types.

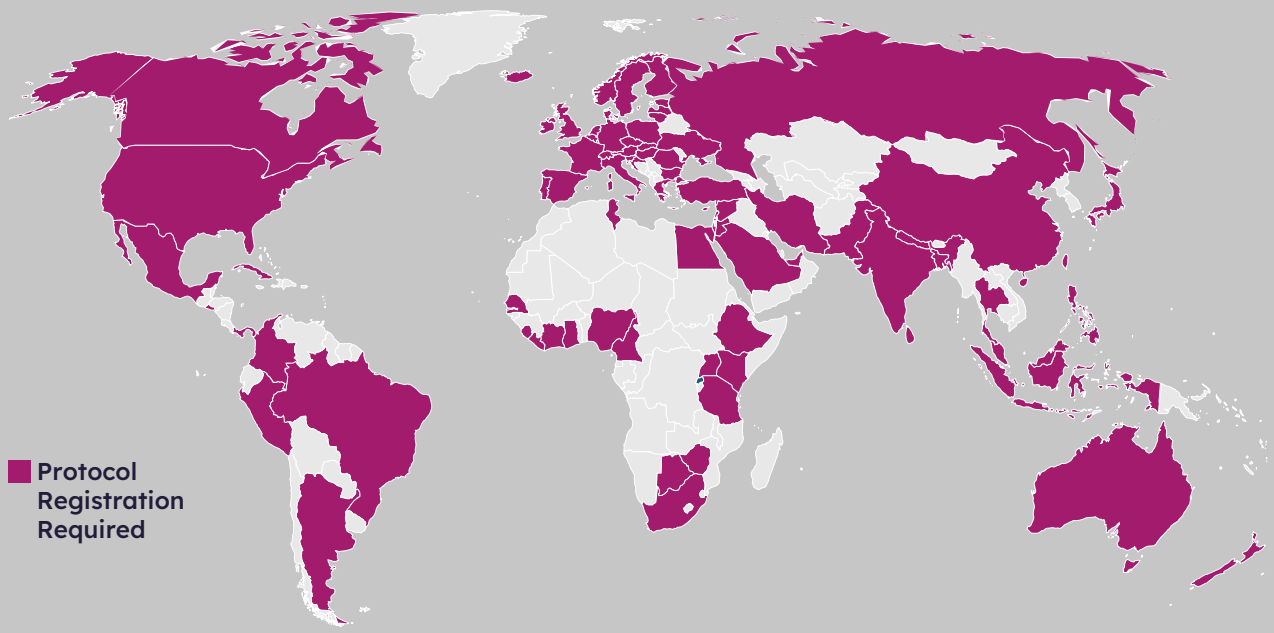
2 STEP 2: Applying filters to refine results

To refine the information displayed, the user applies filters using the study and trial parameters available in TrialScope Intelligence. These parameters allow customization based on:

- **Study/Trial Type:** Interventional, observational/non-interventional, or expanded access/compassionate use
- **Intervention Type:** drug, biological, or vaccine
- **Phase:** bioequivalence/bioavailability studies through Phase I, II, III, IV

For this particular trial, the user selects **"interventional"** as the study type, **"drug"** as the intervention type, and **"Phase I."** With these parameters applied, the country profile displays only the disclosure requirements specifically applicable to these criteria.

Figure 1. Countries requiring protocol registration providing a visual overview of where mandatory clinical trial registration obligations exist worldwide



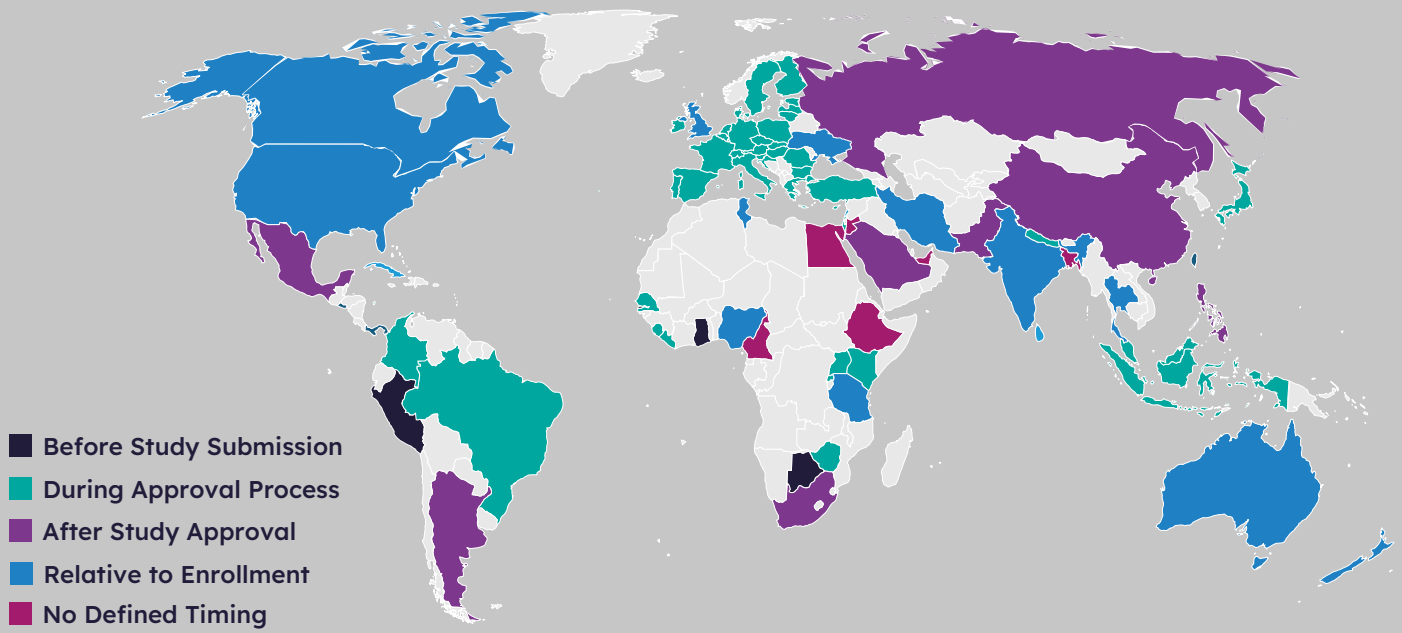
Source: TrialScope Intelligence

3 STEP 3: Examining the Requirement Record

Having established that disclosure obligations exist for their study type, the user navigates from the **Country Profile** to the relevant **Requirement Record**. TrialScope Intelligence maintains over 75 Requirement Records globally, each organized into 10 comprehensive sections containing over 211 data fields. These records convert complex regulatory requirements into actionable, comparable information, enabling precise tracking of requirements across various disclosure components.

The Requirement Record for Switzerland protocol registration indicates that **registration is mandatory** rather than voluntary. Sponsors must register the trial before it starts and within six months after approval has been granted. For Phase I clinical trials where the medicinal product is administered exclusively to adults, certain data elements may initially be excluded from registration but must be entered and published within 30 months after completion or early termination. The record also specifies ongoing obligations.

Figure 2. Protocol registration timing requirements by country, showing whether registration must occur before study submission, during approval, after approval, relative to enrollment, or with no defined timing



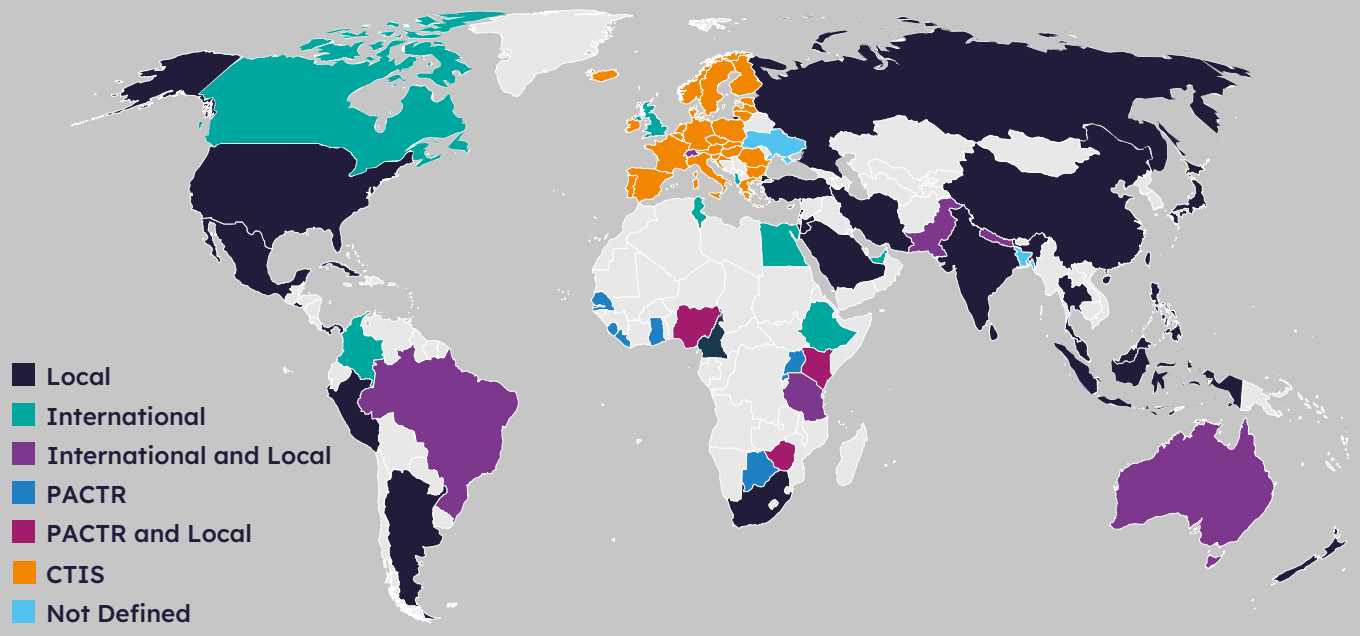
Source: TrialScope Intelligence

4 STEP 4: Identifying permissible registries

The requirement record identifies the permissible registries for Switzerland. **Switzerland requires dual registration:** Sponsors must register in both a WHO Primary Registry (such as ClinicalTrials.gov or another WHO-recognized registry) *and* in the local Swiss registry, Human Research Switzerland (HumRes). Although the record indicates that HumRes is not a WHO-recognized primary registry, registration in it remains mandatory under Swiss law. The record further explains that HumRes receives data through the Business Administration System for Ethics Committees (BASEC), and once the ethics committee approves the trial, information is automatically transferred to the HumRes public portal.

Additionally, the record indicates whether **results disclosure** is required in Switzerland, distinguishing protocol registration requirements from results posting obligations. It notes that sponsors must publish a lay summary of trial results in HumRes within one year after completion, provided in at least those national languages of Switzerland in which persons were recruited.

Figure 3. The permissible clinical trial registries in different jurisdictions; global map categorizing countries' disclosure requirements by permissible registry



Source: TrialScope Intelligence

5 STEP 5: Accessing the registry record for technical implementation

With clarity on disclosure requirements and applicable registries, the user navigates to the relevant registry record for Switzerland, specifically, both ClinicalTrials.gov (or another WHO Primary Registry) and Human Research Switzerland (HumRes). This record outlines the registry's official name, URL, technical support contacts, and access requirements, including account creation procedures.

A dedicated section **maps the exact data fields** required by the registry, translating conceptual disclosure requirements into specific fields, formats, and terminology. This includes character limits, required vs. optional fields, drop-down options, file upload formats and size limits, and any registry-assigned identifiers. This complete field mapping can be downloaded in Excel format for offline reference and internal workflow planning. The record also details the full submission of workflow, including validation checks, amendment processes, and timelines for public posting.

6 STEP 6: Supporting the journey with source documents

Throughout the user journey, from an initial country overview through specific requirement identification to technical registry implementation, the user has access to TrialScope Intelligence's source document library.

For Switzerland, the library includes essential resources such as official guidance on the trial application process and practical guidance documents that help the sponsor navigate the technical submission systems. Source documents are routinely tracked and updated, with superseded versions retained in the library for reference.

7 STEP 7: Monitoring and maintaining compliance

To maintain ongoing compliance awareness, the user can establish alerts within TrialScope Intelligence to **receive notifications** about regulatory updates on a predetermined frequency, such as daily monitoring. These alerts ensure the team is immediately informed when source documents are updated, requirements are amended, or new guidance is published by Switzerland's regulatory authorities. This proactive monitoring capability transforms static compliance documentation into a dynamic regulatory intelligence system, enabling the team to adapt quickly to any changes in the disclosure landscape.

The complete journey: from uncertainty to actionable compliance

The user has returned to their project team with confidence, armed with a complete compliance roadmap for conducting their interventional drug trial in Switzerland:

- ✓ What must be disclosed
- ✓ When disclosures must occur
- ✓ Where submissions must be made across potentially multiple registry systems
- ✓ How to complete the technical registration process

All this is supported by authoritative regulatory sources that validate their approach. And, with alerts configured to monitor regulatory changes, the team has established a sustainable compliance framework that will keep it informed of any developments throughout the trial lifecycle.

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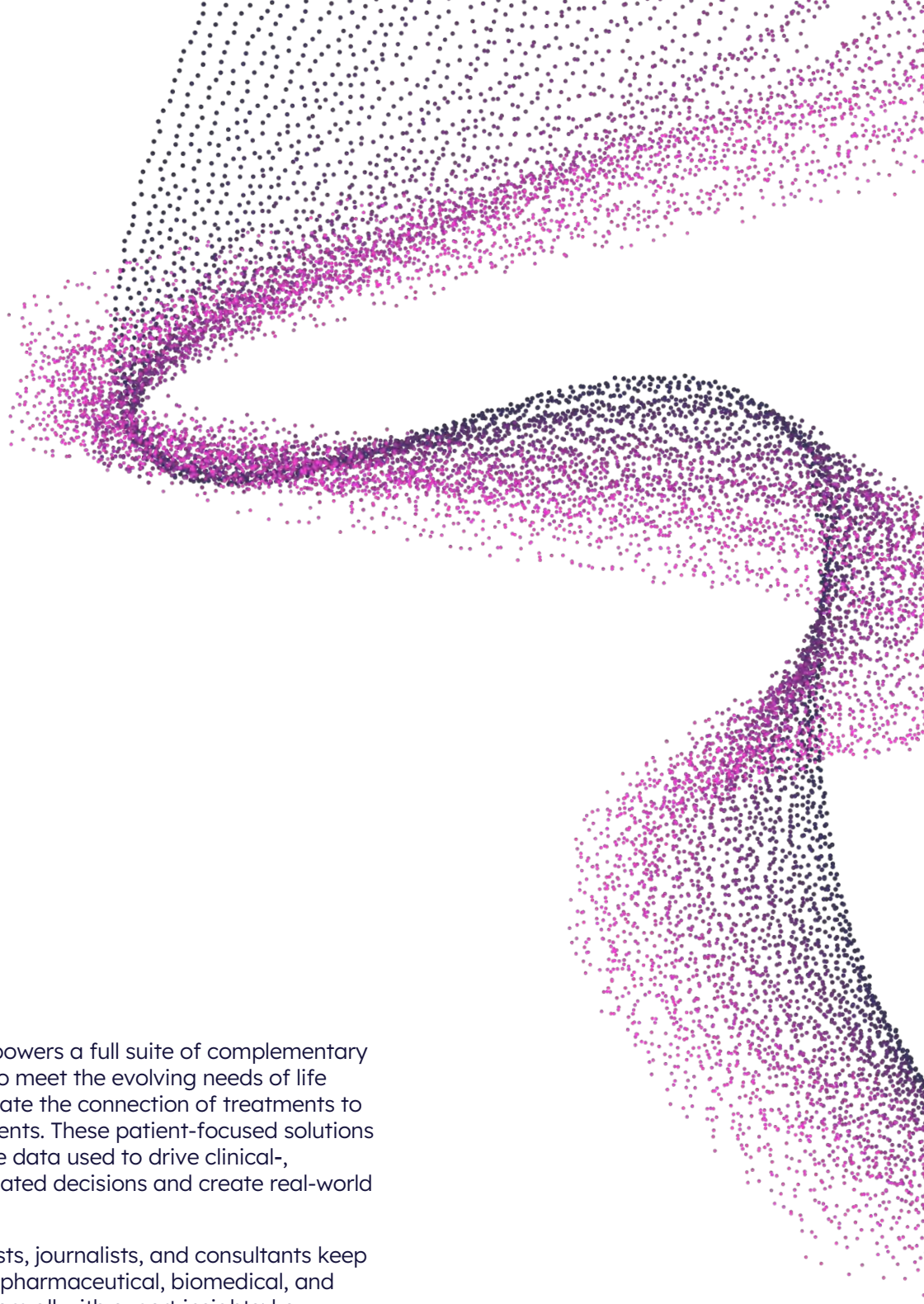

About Citeline

Citeline, a Norstella company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical-, commercial-, and regulatory-related decisions and create real-world opportunities for growth.

Citeline's global teams of analysts, journalists, and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted health science partners, visit Citeline and follow on LinkedIn and X.

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