



## **Case study #1**

Pharmacovigilance for an early access program in 40 countries

**tepsivo**

## Collaboration overview

In 2022, we have supported one of the major biotech companies during a large-scale early access program around the world.

The customer wanted to ensure they have local pharmacovigilance resources in each country and they were looking for a fast setup to meet their EAP requirements.

Scale:

**40**

non-EU countries

Client:

**TOP 20**

US Biotech

Total budget:

**€150k**  
/ year

Estimated savings:

**€400k+**  
/ year



## **Detailed scope**

Complete local PV setup in 40 countries outside of Europe

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LCPPV (+ backup) in 40 countries

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Regulatory intelligence via Tepsivo News

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Tepsivo Platform Local PV Module

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Safety submissions using Safety Reporting case intake tool of Tepsivo Platform



# Why Tepsivo was selected

1

## Incomparable setup speed

Our existing network of local contact persons for PV (LCPPVs) in 150+ countries allowed us to allocate a team of nearly 80 individuals across 40 countries within 2 weeks.

2

## Instant exchange of case reports

Thanks to Safety Reporting tool of Tepsivo Platform, we interconnected the LCPPVs, the client's global ICSR processing team, and individual local authorities around the world.

3

## Full oversight of all data & activities

Customer achieved effortless control by using Tepsivo Platform, its workflow automation and PV modules across all 40 markets - while ensuring legal compliance in each country.

4

## Minutes of admin work instead of hours

We minimized the manual routine workload of every LCPPV and removed needless "project management" tasks (otherwise very typical of such large-scale setups).

“ The large scale and challenging needs of the project were simply a great fit - allowing us to show full potential of Tepsivo solution. And yes, the client was astonished. ”

Dominik Hodbod, CEO of Tepsivo



## Additional outcomes

The automated audit trail of all actions ensured complete inspection readiness and allowed a retrospective view into selected compliance metrics at any time.

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Tepsivo News removed the need to manually search through authority websites for relevant regulatory updates, adding to the complete efficiency of the Tepsivo local PV solution.

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...and of course, we delivered on our key promise of reducing unnecessary costs in pharmacovigilance.

**It's your turn now.**

Contact us and we will establish a truly modern,  
100% compliant PV system for you too.

**tepsivo**

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