



Case study #6

Large scale pharmacovigilance
outsourcing across developing countries

tepsivo

Collaboration overview

One of the major pharmaceutical players was facing the challenge of establishing a local PV infrastructure from scratch in over 50 markets outside of Europe.

What typical PV providers see as a challenge and require months of setup, we managed to have up and running within 2 weeks.

Scale:

50+

non-EU countries

Client:

TOP 20

US pharma

Total budget:

€150k
/ year

Estimated savings:

€400k+
/ year



Challenges

developing markets

The regions to cover included a large number of African countries that have in recent years been imposing new pharmacovigilance rules, especially the requirement on a local contact person for PV (LCPPV).

Legal environment of these regions is dynamic and our client needed a reliable partner with local expertise for these emerging markets - a service not offered by every provider.

system complexity

Also normally, traditional PV companies struggle to coordinate such a large scale of services including many individuals across different time zones. It is standard that they require a “project manager”.

These people constantly exchange emails, schedule meetings, bounce tens of meaningless excel trackers with the 30+ individuals involved, and other mundane admin work; all the while with ballooning costs, cluttering the system, leaving the customer only guessing what actually is happening in their PV system.

Fortunately with Tepsivo Platform, our client doesn't face any of this.



Our solution

Tapsivo Platform and its local PV module (the world's first automation of local PV activities) has given the customer a full view into every piece of data & activities happening around their global PV system.

It has removed the need for any “project manager”, decreased the routine time effort for a LCPV to a minimum by automating regulatory intelligence updates via Tapsivo News as well as by digitizing the safety submissions via the *Safety Reporting* module of Tapsivo Platform; all the while ensuring full legal compliance.

And, of course, we delivered on one of our key promises: large cost reduction.

14

days

was the complete setup
time, including LCPVs

30

local contact persons

appointed in countries
where legally required

24/7

inspection readiness

with the help of automated
audit trail of all actions



Detailed scope

Complete local PV setup in over 50 countries
outside of Europe (MENA, CIS, APEC regions)

Regulatory intelligence via Tapsivo News

Tapsivo Platform Local PV Module

Safety submissions via *Safety Reporting* tool and other local PV work

30 legally required LCPVs (and backup)

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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