



ESPERO

Single source of truth for Protocol Development

30%

Reduction of Protocol
Development time

67

Day reduction of
eCRF builds

\$30M+

R&D cost savings

Espero help you boost your team's efficiency by pre-populating the protocol template, accelerating protocol authoring, capturing data electronically and sending it downstream to source systems.

- Centralized processes and collaboration workflows
- Ability to ingest protocol data from historical sources
- Data-driven protocol design with real-time insights with patient and site feedback for reduced burden
- Automated FDA Submission
- Dynamically generated study documents with 1-click IRB, ICF, IB document generation
- 1-click source system builds (eCRF, ePRO, eCOA)

The screenshot displays the 'Espero IDP Insights Driven Protocol' interface. The main content area shows details for 'Protocol - ADP311_2002' (P-10701). The protocol title is 'A Phase 2b, Multicenter, Double-blind, Placebo-controlled, Dose-ranging Study to Investigate the Efficacy, Safety, and Tolerability of Trabikibart Compared with Placebo in Adult Subjects with Severe Asthma'. The current stage is 'Data Capture' and the status is 'PENDING-DATA CAPTURE'. The interface includes a sidebar with navigation icons, a top navigation bar with tabs for 'Protocol Creation', 'Data Capture', 'Review', 'Approval', and 'Document Generation', and a search bar. The main content area is divided into sections: 'Collaborate & History', 'Details', 'References', 'Feedback Comments', and 'Protocol Instructions'. The 'Details' section is expanded, showing a 'Summary' and a 'Description'. The 'Summary' section includes the protocol title, number, compound number, and short title. The 'Description' section includes an introduction, background, and a list of key features.

Protocol Number	ADP311_2002
Compound Number	Trabikibart
Version	6
Current Stage	Data Capture
Status	PENDING-DATA CAPTURE
Protocol Title	A Phase 2b, Multicenter, Double-blind, Placebo-controlled, Dose-ranging Study to Investigate the Efficacy, Safety, and Tolerability of Trabikibart Compared with Placebo in Adult Subjects with Severe Asthma

Protocol summary	Protocol synopsis	Study design	Study interventions	Study outcomes
Summary Protocol Title Protocol Number Compound Number Short Title	A Phase 2b, Multicenter, Double-blind, Placebo-controlled, Dose-ranging Study to Investigate the Efficacy, Safety, and Tolerability of Trabikibart Compared with Placebo in Adult Subjects with Severe Asthma ADP311_2002 Trabikibart Dose-ranging study			

Phase 3 results	
Description	A Phase 2b, Multicenter, Double-blind, Placebo-controlled, Dose-ranging Study to Investigate the Efficacy, Safety, and Tolerability of Trabikibart Compared with Placebo in Adult Subjects with Severe Asthma
Introduction	CSL Behring (CSLB) has developed Trabikibart for use in chronic pulmonary disorders such as severe obstructive pulmonary disease (COPD), as well as cutaneous sarcoidosis. It is a novel monoclonal antibody that targets the interleukins IL-3, IL-5, and granulocyte-macrophage colony-stimulating factor (GM-CSF) from the beta chain (βc) expressed by a subset of inflammatory myeloid cells, ie, eosinophils, neutrophils, monocytes, basophils, and dendritic cells. Inhibition of IL-3, IL-5, and GM-CSF signaling is expected to result in a reduced inflammatory response in patients afflicted by disorders driven by Type 2 (T2) and non-T2 inflammatory pathways.
Background	Interleukins IL-3, IL-5, and GM-CSF are related cytokines that regulate the growth, differentiation, and survival of hematopoietic cells [Martinez-Moczygemba and Huston, 2003; Wang et al, 2009]. They are important mediators of immunity but can also contribute significantly to the development and progression of chronic and allergic pathologies such as asthma and COPD. The receptor complex for each of these cytokines is composed of a common alpha (α) chain and a dimer of the beta chain (βc) subunit that is shared by all 3 cytokines [Carr et al, 2001]. Trabikibart specifically binds to the human βc receptor subunit, potentially inhibiting its biological activity [Panousis et al, 2015]. Trabikibart is being developed for the treatment of severe asthma and has been investigated in a first-in-human (F1H) multiple ascending dose study in patients with mild-to-moderate asthma and healthy volunteers.
Acronym	ADP311_2002
Primary Completion Date	December 31, 2024
Version	6
Manufacturer Name	AdmePharma LLC
Manufacturer Address	AdmePharma LLC 1020 Second Avenue

Case study

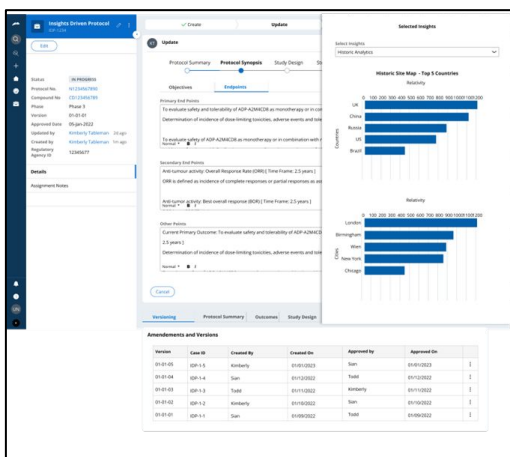
Espero drives operational efficiency for Top-10 Pharma with an aim to reduce \$30M+ in R&D costs

In a global top-10 pharma deployment ESPERO delivered IDP to connect data sources to provide protocol insights, and allow for cross-team collaboration through streamlined workflow and feedback mechanisms.

The primary objective was to facilitate the reuse of eProtocol data downstream to accelerate the creation of the Case Report Forms(eCRF), eCOA, and IRT set-up.

1

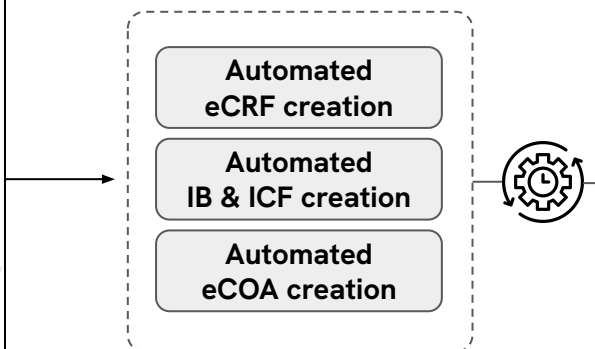
Protocol Development



30% reduction of Protocol Development time

2

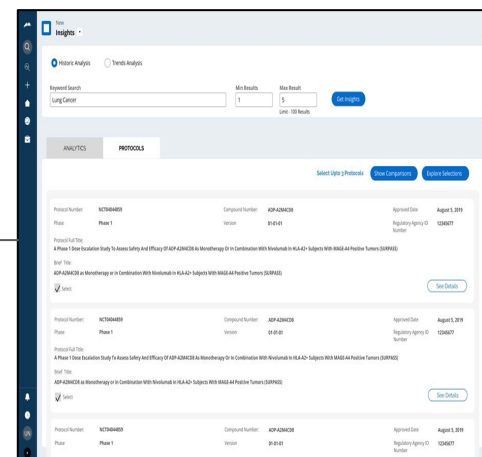
Operational Efficiency



67 day reduction in eCRF build and 1-click automated generation of IRB documents, Investigator Brochure(IB) and Informed Consent Forms (ICF).

3

Protocol Amendment



Phase III studies have on average 3.5 protocol amendments, as the protocol is re-drafted with ESPERO, a significant time savings can be realized in rebuilding ICF, IB, and eCRF dynamically for Mid-study updates.

Why Espero



eCRF automation



Collaborative workflow



Dynamically generate study documents