
PRINEOS
LIFE SCIENCES, TOGETHER

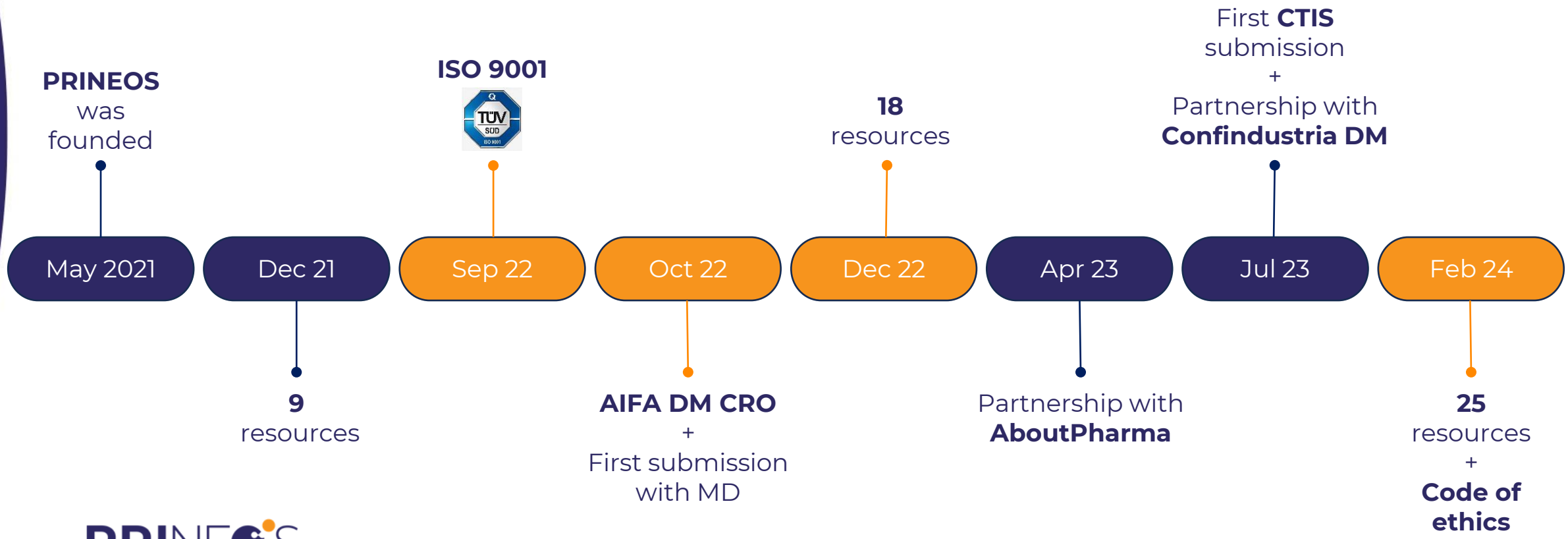
PRINEOS

Company overview

About us & timeline

PRINEOS is a **strategic consulting** company operating in drug, medical device and food supplement industries.

As **CRO** we support our clients during the planning, execution and reporting of clinical studies and investigations.



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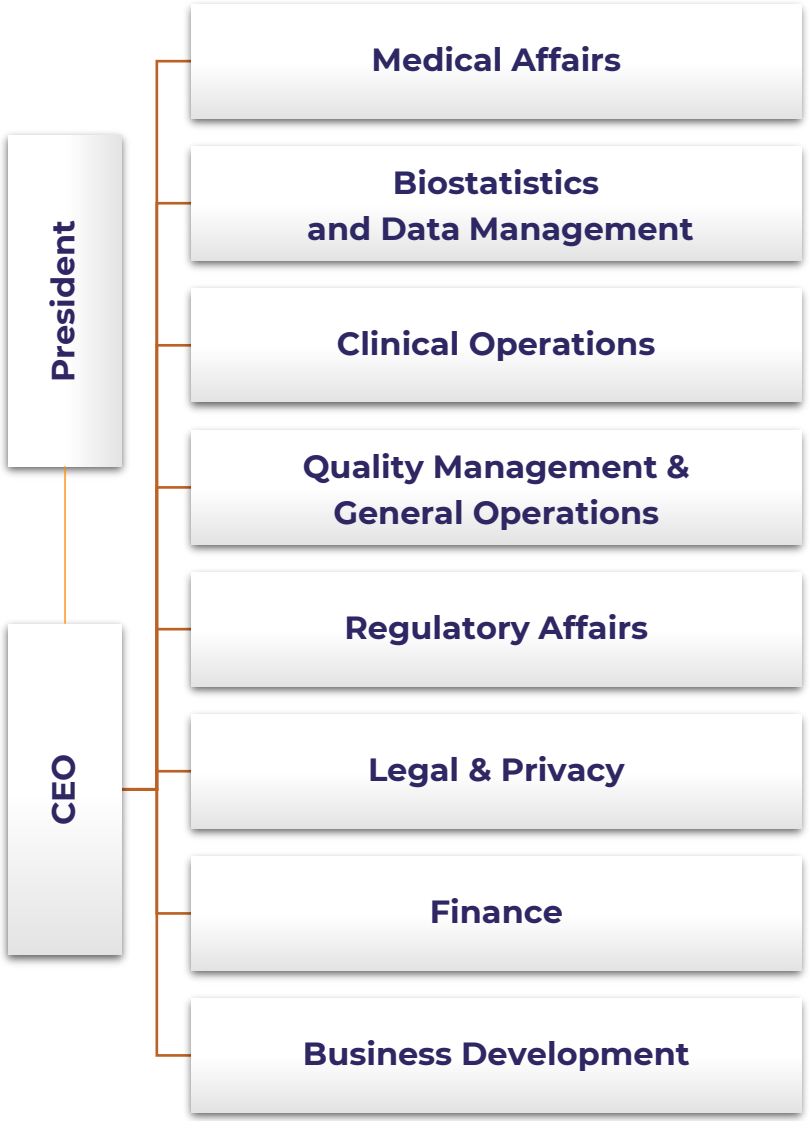
PRINEOS team



Employees are at the very core of our organization and their development and training is key for our success

21	Employees in Q1 2024
4	Consultants
100%	of permanent contracts
1000+	hours of training

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Our expertise in Clinical Research

PRINEOS team has more than 25 years of scientific, medical and biostatistical know-how, as well as sound clinical and regulatory experience following clinical studies on **drugs**, **medical devices** and **nutraceuticals** across many therapeutic areas and all clinical trials phases (**I, II, III and IV**), some therapeutic areas include:

- **Oncology**
- **Neurology and Psychiatry**
- **Rheumatic and Musculoskeletal Disorder**
- **Gastrointestinal and Hepatology**
- **Onco-Haematology / Haematology**
- **Dermatology**
- **Endocrinology and Metabolic Diseases**
- **Infectious Diseases**
- **Cardiovascular Diseases**
- **Ophthalmology**
- **Respiratory Diseases**
- **Rare diseases and orphan drugs**

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services in clinical trials

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PRINEOS services on clinical studies

CLINICAL STUDIES

Medical Writing activities on study and patient documentation

- Chief Medical Officer
- Medical Manager
- Medical Advisor
- Head of Biostatistics
- Senior Biostatistician

Biostatistics activities

- Head of Biostatistics
- Senior Biostatistician
- Biostatistician

Data Management and eCRF development and management

- Head of Biostatistics
- Senior Data Manager
- Data Manager
- Biostatistician

Feasibility and CA/EC submission processes management

- Chief Operating Officer
- Clinical Project Manager
- Clinical Trial Coordinator

Project Management, vendor oversight and Monitoring

- Chief Operating Officer
- Clinical Project Manager
- Clinical Trial Coordinator
- Clinical Research Associate

Study documentation management

- Chief Operatng Officer
- Clinical Project Manager
- Clinical Trial Coordinator

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Our services in clinical studies and investigations

START

STUDY PLANNING AND DESIGN

1

- Country & Site Feasibility
- Site Selection
- Literature search and review
- Study concept and design
- Scientific Advice
- KOL mapping and advocacy
- EC and CA submission
- Clinical Trials Agreements

STUDY EXECUTION

2

- KOL and Advisory Boards Management
- Project Management
- Site Monitoring activities
- Interim Analysis
- Management of TMF

STUDY COMPLETION

3

- Statistical Analysis
- Results interpretation
- Clinical Study Report
- Dossier preparation
- Publications
- Market Access

END

SUPPORTED BY

Regulatory Strategy | Legal & Privacy Compliance | Clinical Development Plan | Training

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regulatory services

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Regulatory Affairs

PRINEOS supports the client for all needs related to drugs and medical devices, carrying out projects from their very first phase up to their completion:

Medical devices:

- Technical Documentation (drafting and update)
- Risk Analysis
- Clinical Evaluation Plan & Report
- Usability in accordance with ISO 62366
- Post Market Surveillance, Post Market Clinical Followup, Periodic Safety Update Report
- Summary of Safety and Clinical Performance
- Biological Evaluation Plan e Report
- Worldwide products registration
- Relationship with Notified Bodies and Competenet Authority
- Regulatory Due Diligence

Medicinal products:

- Preparation of registration dossier (forms 1-5) in CTD and e-CTD format
- Management of the procedure and contacts with the local authorities
- Maintenance of drug approvals: preparation of modules and quality, pre-clinical and clinical overview (modules 3,4 and 5) for variations, renewals and line extension
- Due diligence
- Dossier gap analysis
- Extra EU registration
- Evaluation of regulatory compliance of medical and scientific information material for ethic and OTC drugs

PRINEOS

thank you
danke
謝謝
ngiyabonga
شكراً جزيلاً
рахмат
Баярлалаа
спасибо
teşekkür ederim
gracias
merci
obrigado
dziękuję
bedankt
go raibh maith agat
mochchakkeram
sukriya
kop khun krap
terima kasih
grazie
arigatô
takk
dakujem
мерси
감사합니다
ありがとう
ευχαριστώ
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dank je
mersi
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tack
spas
kia ora
faafetai lava
vinaka
спасибі
blagodaram
misaotra
matondo
paldies
grazzi
mahalo
хвала
asante
manana
obrigada
tenki
murakoze
chokrane
mamnun
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dankie
nanni
nandri
dhanyavad
hvala
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mercé
trugarez