One global partner for paediatric development

ASPHALION
Knowledge from experience

One global partner for paediatric development

PIP / iPSP

Paediatric development programme covering all relevant age groups, from birth to under 18 years, unless waived or deferred.

EU	UK	US
PIP	**PIP**	**iPSP**
EMA	MHRA	FDA

Asphalion aligns strategy, submission timing and life-cycle obligations across regions.

Development plan • Paediatric age subsets • Studies, formulation and timelines

ASPHALION
Knowledge from experience

Navigate paediatric development across the EU, UK and US

EU PIP — EMA

PLAN	PIP matrix & regulatory strategy
ENGAGE	Pre-submission interactions
PREPARE	PIP writing & KEF
RESPOND	RSI responses
MAINTAIN	PIP annual reports & PIP modifications
VERIFY	Request for compliance check

EMA class-waiver requests

UK PIP — MHRA

ADAPT	EU PIP adaptation
PREPARE	UK PIP writing & KEF
SUBMIT	MHRA webform preparation
RESPOND	RSI responses
MAINTAIN	PIP annual reports & PIP modifications
VERIFY	Request for compliance check

US iPSP — FDA

ADAPT	iPSP adaptation from EU PIP
PREPARE	Initial iPSP
SUBMIT	Cover letter & FDA form
RESPOND	Follow-up responses to FDA questions
MAINTAIN	Amended iPSP

Asphalion provides continuity from initial planning through regulatory maintenance.

EU focus: Timelines and implementation of EU new Pharma legislation

Objectives

- **Advance strategic priorities**
- **Reducing procedural complexity**
- **Reducing administrative burden**
- **Modernise regulation**

Implementation context

Dec 2025
Political agreement

2026
Expected adoption / entry into force

2026–2028
Transition and guidance

2028
Expected applicability

Impact on the paediatric regulatory framework

The reform incorporates the paediatric medicines provisions into the new EU Pharmaceutical Regulation, replacing Regulation (EC) No 1901/2006.

New PIP pathway under the reformed EU regulation

The emerging framework introduces a targeted, more iterative pathway for eligible paediatric development programmes.

CURRENT

Complete PIP

COMPLETE PIP

Timing, studies and measures are defined at initial agreement.

EMERGING

Targeted stepwise pathway

INITIAL PIP
Available information and initial strategy

→

UPDATED VERSIONS
Planned updates as evidence matures

→

FINAL PIP
Complete paediatric development programme

Eligibility and scientific justification will determine whether the targeted pathway is appropriate.

KEY SHIFT For eligible programmes, the PIP may evolve through structured, evidence-driven life-cycle management.

The targeted initial-PIP pathway is not expected to be the default route for every programme.

ASPHALION
Knowledge from experience

ASPHALION: Proven experience in PIP/iPSP and end-to-end support

40+ paediatric projects delivered across the EU, UK and US, from PIP strategy to life-cycle maintenance.

40+

Paediatric Investigation Plan projects

EU, UK & US
PIP and iPSP support

THERAPEUTIC AREAS
Rare diseases, dermatology, respiratory, immune-system, infectious disease and more

MODALITIES
Small molecules, biologics, ATMPs

01 **STRATEGY & PATHWAY**
Regulatory strategy, pathway advice and pre-submission meetings.

02 **PIP WRITING & SUBMISSION**
Full PIP preparation and submission, including product-specific waiver and class waiver applications.

03 **MAINTENANCE & UPDATES**
Support for modifications to agreed PIPs/iPSPs, responses to agency questions, and EMA annual reports.

04 **iPSP (US) & EU & UK PIP ALIGNMENT**
Coordinated PIP/iPSP strategy to align EU, UK and US plans.

05 **EMA / UK PIP COMPLIANCE CHECK**
Support for full or partial compliance checks by EMA/PDCO & MHRA before MAA or variation validation.

06 **AD-HOC EXPERT SUPPORT**
Expert support across your paediatric development programme.

LET'S TALK! Planning a paediatric programme? We can help you develop the right PIP strategy from day one.

Contact us!

info@asphalion.com
www.asphalion.com

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