

Accelerated Coverage Pathways for Innovations: A European Mapping

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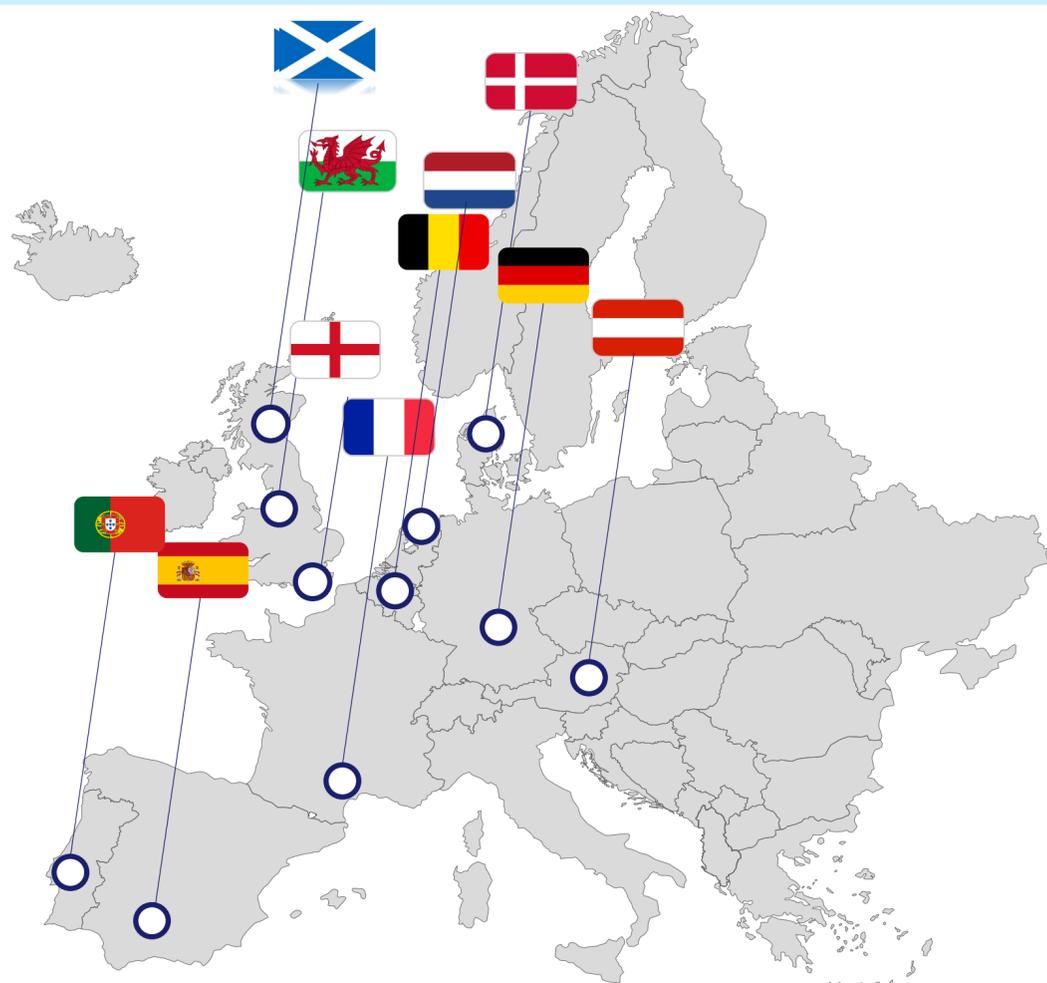


Identified Accelerated Coverage Pathways for Innovation (ACPI's)

So far 20+ Pathways have been identified across Europe, each with their own scope, evidence requirements, stakeholders, access pathways and timelines

Definition

Accelerated Coverage Pathways for Innovations (**ACPI's**) are **bilateral or multilateral agreements** that enable **patient access to a health technology** subject to specific conditions **outside the general reimbursement/funding frameworks**



Identified Pathways¹



Austria

- Provisional/analogous MEL procedure codes



Belgium

- Limited Clinical Application



Denmark

- Patient outcome-based procurement of total knee joint replacements



England

- Accelerated Access Pathway (AAP)
- Artificial Intelligence in Health and Care Award²
- Commissioning through Evaluation (CtE)
- Innovation Technology Payment (ITP) program²
- NHS Innovation Accelerator²



France

- Article 51 of Social Security law (2018 & 2019)
- Health Economic Research Program – PRME
- Hospital Clinical Research Program – PHRC
- Innovation Package (Forfait Innovation)
- Repository of innovative acts outside the nomenclature of biology and anatomical pathology - RIHN



Germany

- 137e - trial regulation
- 137h – Trial regulation for highly invasive medical devices
- Innovation fund
- Model projects
- NUB
- Selective contracts



Digital Health Applications (DiGA)

Netherlands

- Innovation for small-scale experiments
- Subsidized Trial for Innovation for the Basic Health Packet
- Promising care



Portugal

- Medical Device Reimbursement



Scotland

- IMTO Process from Health Technology Scotland



Spain

- Public Procurement of Innovative Technologies
- Supervised Use
- Monitoring Studies



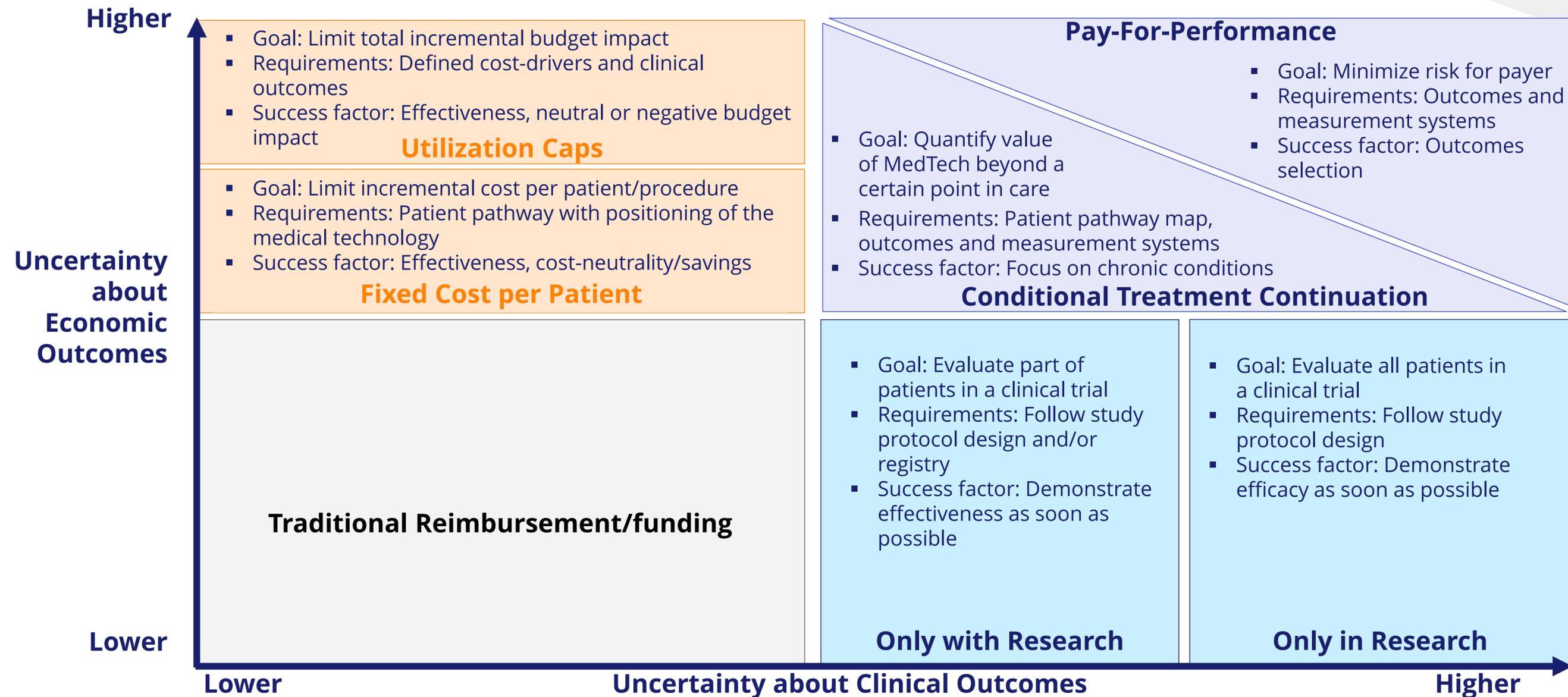
Wales

- NHS Wales

Note: ¹Swiss pathways not included in the list ²Part of the Accelerated Access Collaborative, the umbrella department overseeing different programs, including 3 ACPI's.

Taxonomy of Accelerated Coverage Pathways for Innovations

The Pathways can be clustered in different categories depending on whether they want to answer the clinical and/or economic uncertainty of a health technology



Accelerated Coverage Pathways for Innovations in Germany



Germany is a strong innovation adopter with seven ACPI's supporting companies needs at different stages of the Product Life Cycle. With the Digital Health Applications (DiGa) it has a dedicated pathway to fast track digital innovations into the German reimbursement system.

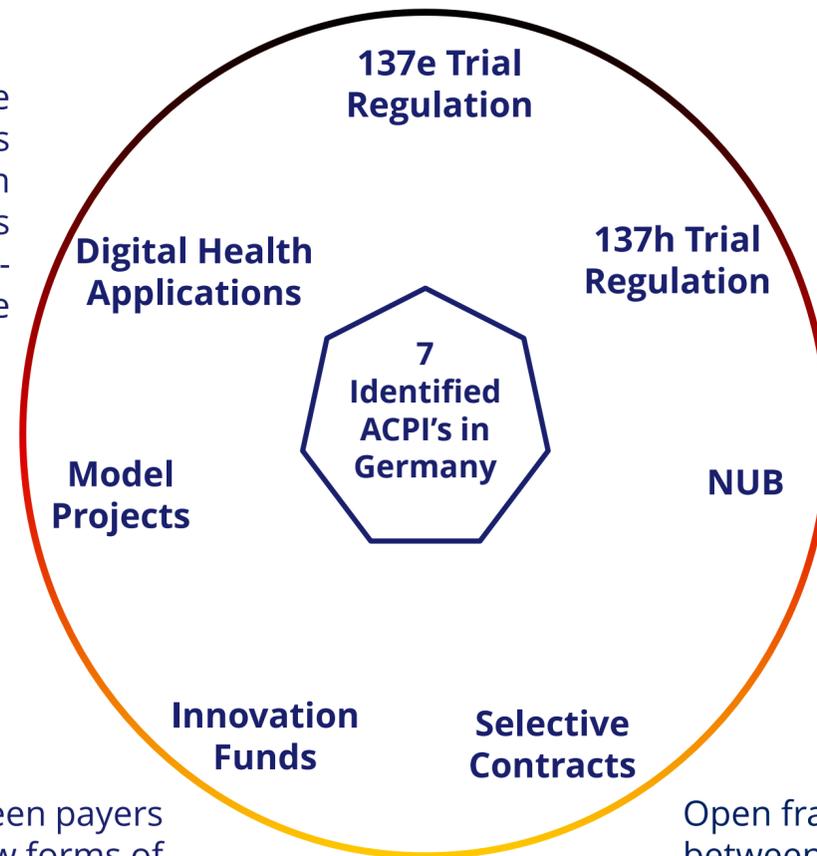


Diagnostic or therapeutic methods that show a potential benefit but for which available evidence is not sufficient to decide on inclusion as a benefit within statutory health insurance

Fast-track procedure to give access to digital technologies that support the detection and treatment of diseases and a self-determined, health-promoting lifestyle

Technologies for which the health technology assessment by the G-BA is paused due to lacking clinical data

Collaborations between payers and providers for new forms of care that improve quality and effectiveness, requiring extensive economic evidence



Early benefit assessments for innovation funding of high-risk devices used in inpatient settings

Program for high-cost medical technologies in the inpatient hospital setting (includes pharmaceuticals & diagnostics) when the standard hospital DRG is insufficient

Open frameworks for collaboration between payers and providers, especially aimed at improving patient pathways between in- and out-patient care

German Accelerated Pathways: General Comments

- For the **137e Trial Regulation** sufficient scientific evidence should already exist as a basis to plan a study that supports a reimbursement decision
- For **selective contracts**, devices need to be CE-labelled and clear economic evidence (e.g. budget impact) is required when engaging with payers – it is possible that after enough contracts, the G-BA will require a formal HTA
- After obtaining the CE-label, the **Digital Health Applications** pathway can be of interest to fast-track low-risk digital innovations into the system
- The **German NUB program** is generally seen as one of the more well-regarded ACPI's in Europe
- With **seven different ACPI's**, Germany can be seen as strong in the adoption of innovation, however the significant evidence requirements make the programs challenging for SME's

Overall Country Ranking

Accelerated Coverage Pathways for Innovations in France



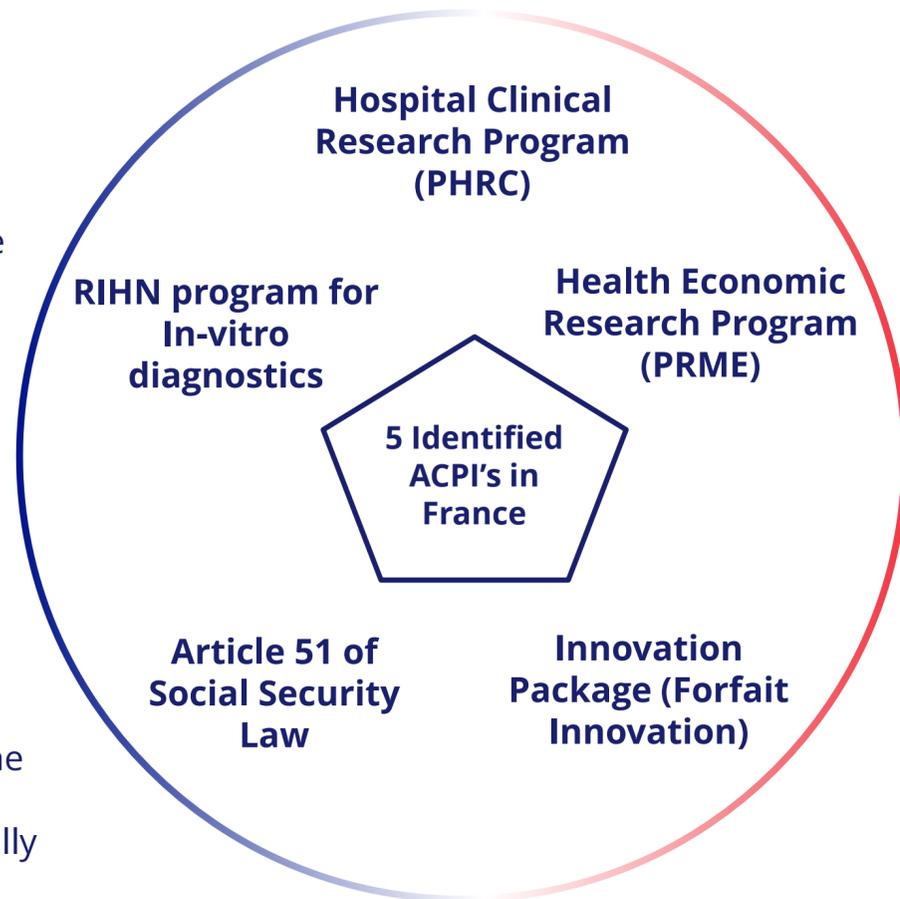
France counts five ACPI's each with a distinct purpose in the Product Life Cycle. With the RIHN program it has the only ACPI uniquely dedicated to in-vitro diagnostics.



Scope: The program dedicates a budget to perform clinical research for drugs or medical devices at French hospitals.

Scope: Innovative in-vitro diagnostics that have insufficient evidence to be included in the nomenclature of medical biological acts NABM

Scope: Innovations in the organization of health and medical-social sectors with the objective of reproducing and spreading the results nationally



Scope: Demonstrate clinical and health economic utility for innovation, for which clinical effectiveness was previously validated

Scope: Combining evidence generation to fill evidence gaps for breakthrough innovations with the managed introduction of the technology

French Accelerated Pathways: General Comments

- France has adopted a PLC approach to their ACPI's:
 - **Early Product life cycle** : PHRC & PRME with clinical and economical evidence respectively
 - **Post CE-mark**: Forfait Innovation & Article 51 focused on evidence generation and innovations in the organization of care.
 - The **dedicated IVD** is a welcome program, especially for those manufacturers with innovative IVD solutions
- Overall, the **French system is highly centralized**, which lends itself to scalability of the programs
- **Key concerns with the French system include the decision making process and how innovation is defined.** Increased collaboration and dialogue would continue to strengthen the French ACPI system

Overall Country Ranking

Accelerated Coverage Pathways for Innovations in England



England counts five ACPI's supporting companies needs at different stages of the Product Life Cycle. Three of these programs are part of the Accelerated Access Collaborative. The AI in Health & Care Award is an accelerated pathway to coverage dedicated for AI technologies.

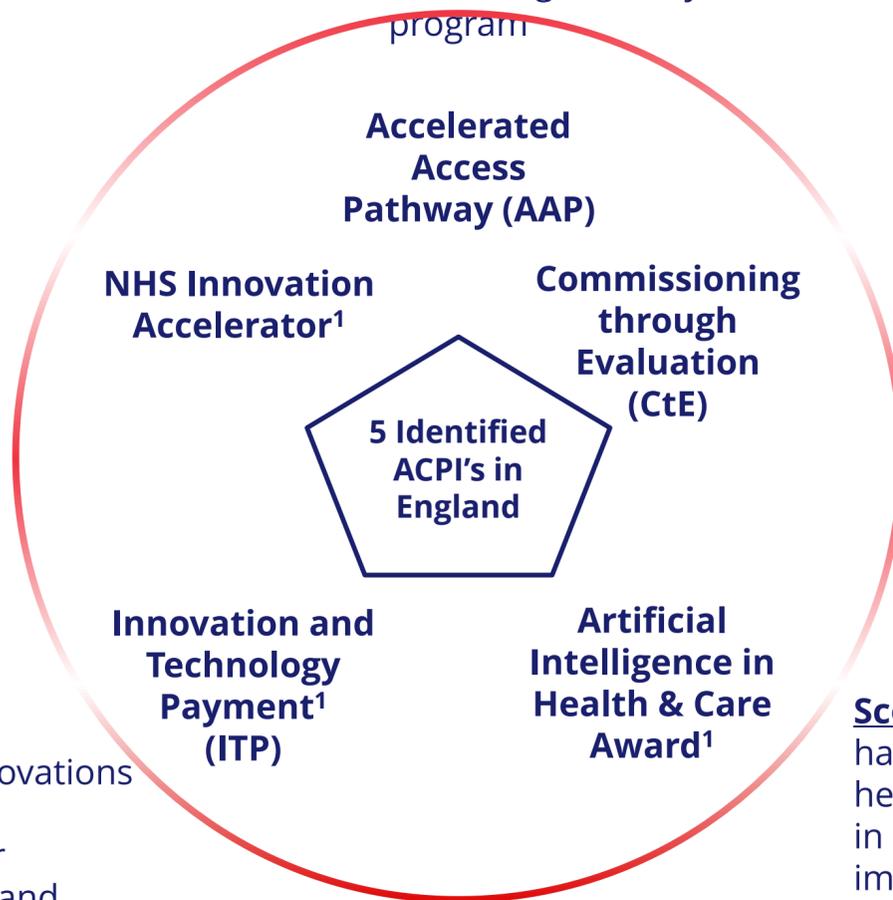


ACCELERATED
ACCESS
COLLABORATIVE

Scope: Aims on individuals representing compelling, evidence-based innovations combined with a convincing, ambitious plan for how to scale the innovation for greater patient benefit

Scope: supports low cost innovations (devices, digital platforms & technologies) that can deliver significant patient outcomes and savings in a short-term horizon (ca. 12 months)

Scope: The AAP aimed to get strategically important, cost-effective products into the NHS as rapidly as possible within NHS resource constraints through an only in research program



Scope: Enabling the collection of valuable new clinical and patient experience data for treatments that are not currently routinely funded by the NHS, but show significant promise for the future

Scope: AI technologies that may have a variety of applications in health and social care (improvement in patient outcomes, and/or improvement in patient experience, and/or improvement in operational efficiency)

English Accelerated Pathways: General Comments

- The **policy environment for England is one of the biggest detractors** for English ACPI's. There has been significant change in the surrounding policy landscape (NHS Long Term Plan), and the programs themselves, to fully support the introduction of innovation
- The **Accelerated Access Collaborative is an umbrella program with 12 sub-programs** that span the entire product lifecycle continuum. Not all are MedTech eligible as some are for clinical innovation
- **Academic Health Science Networks/Centers** can be strong enablers for the introduction of medical technologies to healthcare systems
- The **Artificial Intelligence in Health & Care Award** program can support pre-CE mark solutions that have an AI or digital component and support the improvement of patient experience

Overall Country Ranking

Contact Us

For detailed information on any of these Accelerated Coverage Pathways for Innovation (ACPI), please contact



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Richard Charter has over 15 years of experience in both financial and health economics, with a singular and comprehensive focus on the MedTech market access space.

Currently, Richard is the co-chair of the ISPOR Medical Device Special Interest Group, past chairperson of the MedTech Europe Evidence & Payers Working Group, CO-chair of the HTAi Medical Device Interest Group, and the industry advisor to the EU-funded Horizon 2020 COMED initiative on cost and outcomes measurement for medical devices.

Richard earned his master's degree in Healthcare Management, Economics and Policy (MIHMEP), at SDA Bocconi. Richard has also completed the Harvard Business School Intensive Seminar on Value-Based Healthcare and has successfully helped guide various Market Access and Value-Based Healthcare (VBHC) pilot projects around Europe.

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