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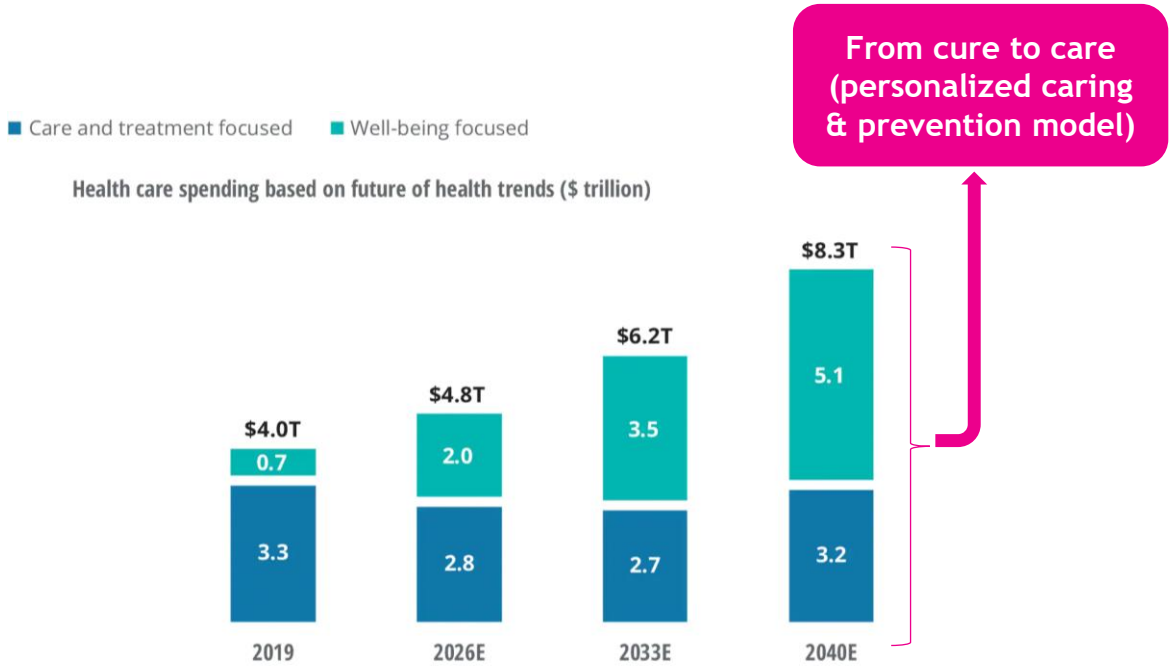
How Are European Countries Assessing Digital Health Technologies (DHTS)?

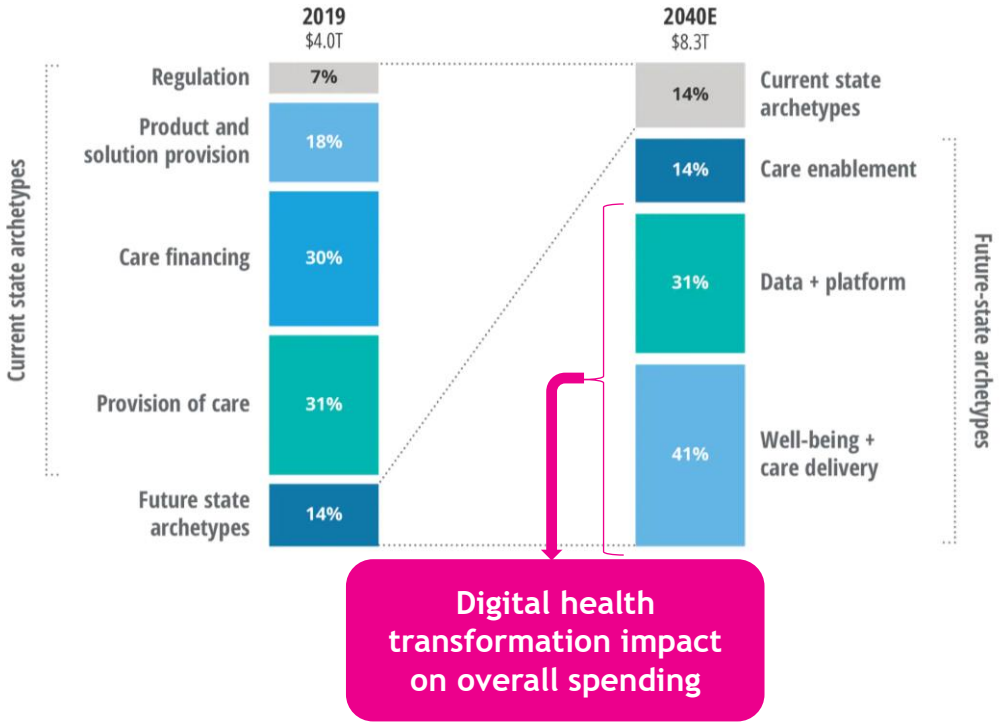
A Comparison of DHT Health Technology Assessments (HTAS) Across France, Germany and the UK

Paradigm shift in the provision and financing of health(care) in the future: key role of prevention (well-being and early detection)

- By 2040, two-thirds of healthcare spending will likely be on prevention (well-being and early detection) of diseases



- By 2040, healthcare revenue will shift to organizations focused on well-being & care delivery, data & platform, and care enablement



Source: Deloitte Analysis/Deloitte Insights

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Digital health technologies classification is essential to understand products' regulatory frameworks and evidence requirements

Digital Health

i.e.: User-facing technologies, Health Information Technology, Consumer health information, Telehealth, Decision support software (that do not require medical input data and do not make recommendations), Enterprise support, Clinical care administration & management tools.

Technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations. Usually do **not meet the regulatory definition of a medical device** and do not require regulatory oversight nor clinical evidence

Digital Medicine

i.e.: **Digital diagnostics, Digital biomarkers, Electronic clinical outcome assessments, Remote patient monitoring**, Decision support software (that relies on medical data inputs and process/analyse information), Digital companion, etc.

Evidence-based software and/or hardware products that **measure and/or intervene** in the service of human health. **Usually require regulatory oversight and clinical evidence**,

Digital Therapeutics

Software that: **Treat a disease, Manage a disease, Improve a health function**

Deliver evidence-based therapeutic interventions to **prevent, manage, or treat a medical disorder or disease**. Must adhere to technology best practices relating to design, clinical evaluation ,usability, and data security. Require **certification by regulatory** authorities to support product claims of risk, efficacy, and intended use. **Clinical evidence and real-world** outcomes are required for all products.

Adapted from: www.healthxl.com/blog/digital-health-digital-medicine-digital-therapeutics-dtx-whats-the-difference

Digital healthcare products face a variety of common challenges across all markets

Common challenges include:

- Lack of clear regulatory and reimbursement frameworks with limited opportunity for clear evidence generation planning
- Heterogeneous market access landscape with a variety of stakeholders involved
- Poorly understood clinical and economic impact
- Lack of consensus on assessment of public health benefit and definition of endpoints

In addition to these, there are country specific challenges to be aware of which reflect the heterogeneity of regulatory processes and value assessment frameworks in each market

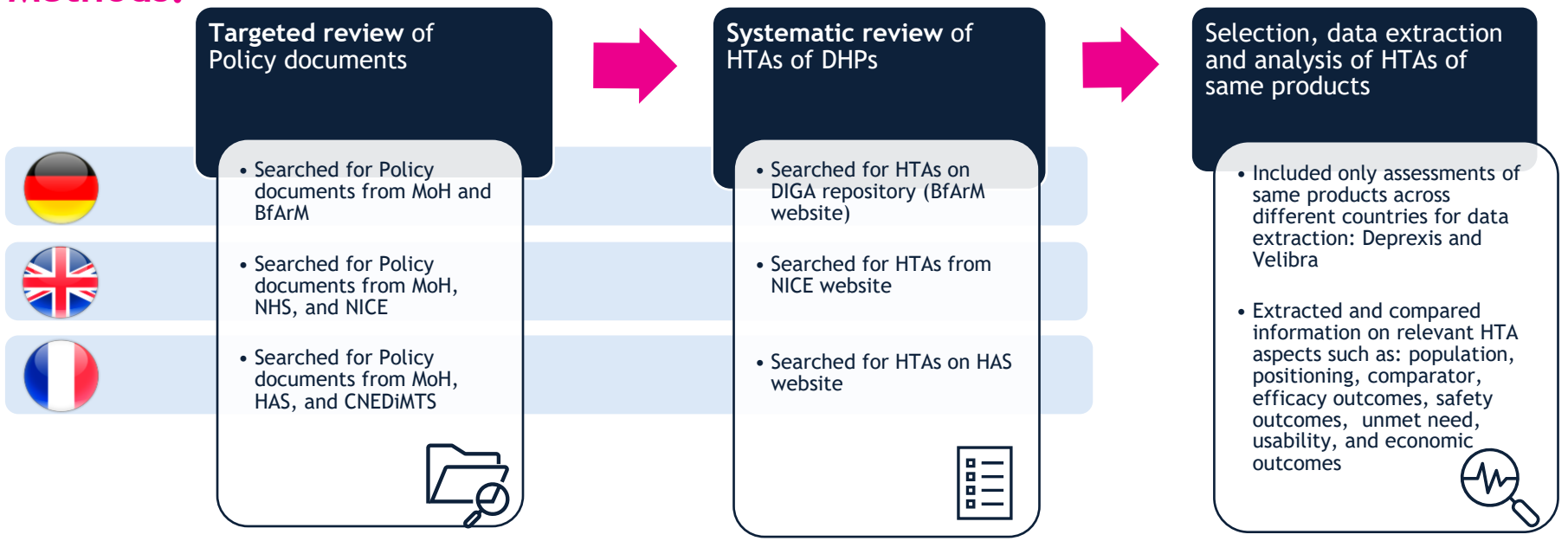
- Clinical and economic evidence requirements differ by individual country assessment bodies including CNEDiMTS, NICE/NHSx and BfArM and are yet to be determined in other countries
- New technologies may also have coding requirements at national level
- Alignment to DRG/HRG codes at local level may also affect uptake

We aimed to analyse and compare current HTA frameworks and assessments of DHPs across major EU countries

Objectives:

1. Review assessment and access frameworks across major EU countries: Germany, UK, France (and Italy).
2. Systematically identify published HTAs of DHPs across Germany, the UK, and France.
3. Analyze and compare published HTAs for the same products across the three countries.

Methods:



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Current assessment and access frameworks vary greatly across countries

Only Germany and the UK have DHP specific assessment frameworks

Only the UK has structured economic assessments for DHPs (in Italy it is proposed, in France only for substantial costs). In Germany, no economic analysis performed.

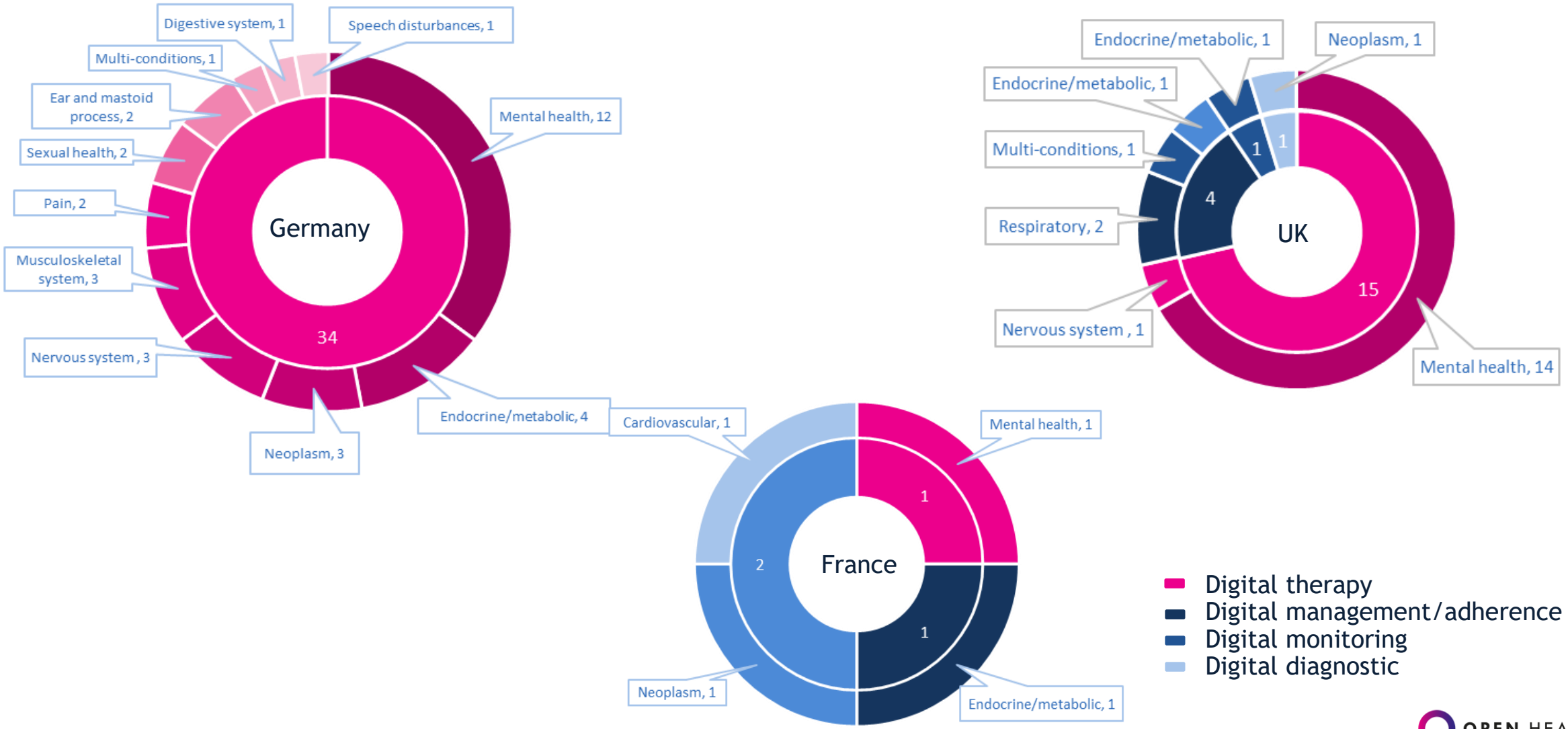
Countries	Relevant stakeholders	DHP/DTx-specific HTA	Technical evaluation	Clinical evaluation	Economic evaluation	DTx already approved	Centralized market entry
Germany	- BfARM (HTA) - GKV-SV (Price)	✓	✓	✓	✗	✓	✓ DiGA
UK	- NHSx/NICE (HTA) - Local (Price)	✓	✓	✓	✓	✓	✗
France	- CNEDiMTS (HTA) - CEPS (Price)	✗	✓	✓	✓ §	✓	✓ LPP
Italy*	N/A	✗	✓	✓	✓	✗	✗

All countries require high-level clinical evidence from RCTs – in Germany there is an additional focus on patient-relevant outcomes: DHPs can apply for claim of improvement of patient-relevant improvement of structure and processes rather thank clinical benefit

Only Germany and France have centralized market entry frameworks with already reimbursed DHPs

*Only proposals; no active legislation yet in place. §Economic evaluation in France done only if the intervention would have a substantial financial impact on the system.
Abbreviations: DHP, digital health products, DTx, digital therapeutics

Most DHPs assessed are in **mental health**, with **DTx** being the overall most assessed digital products



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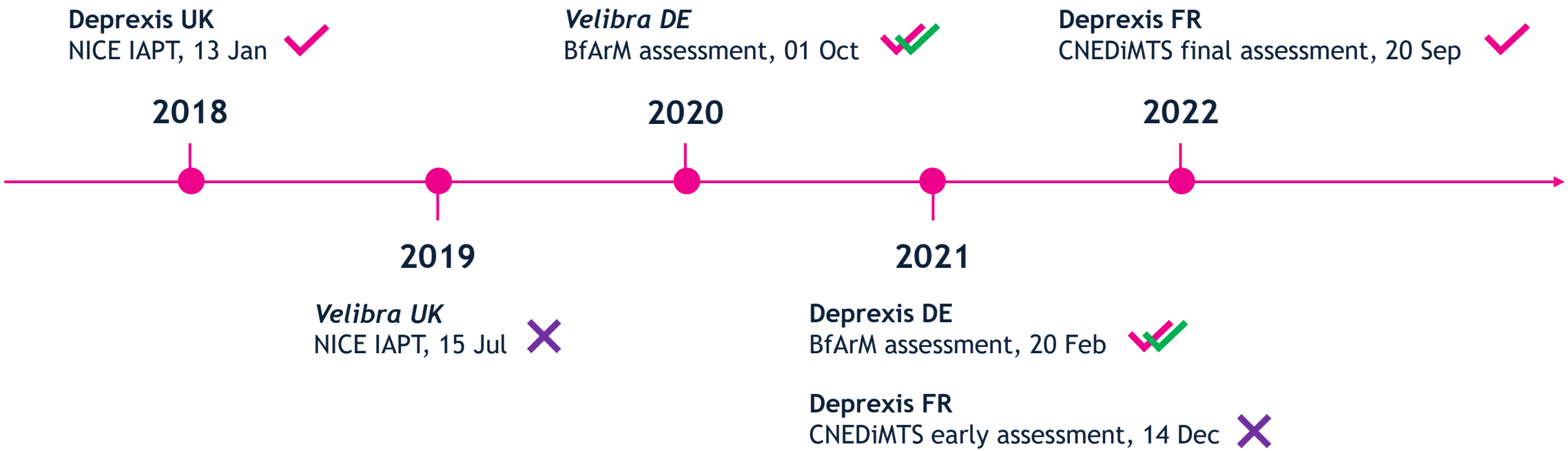
Only two DHPs have been assessed across multiple countries: **Deprexis and Velibra**



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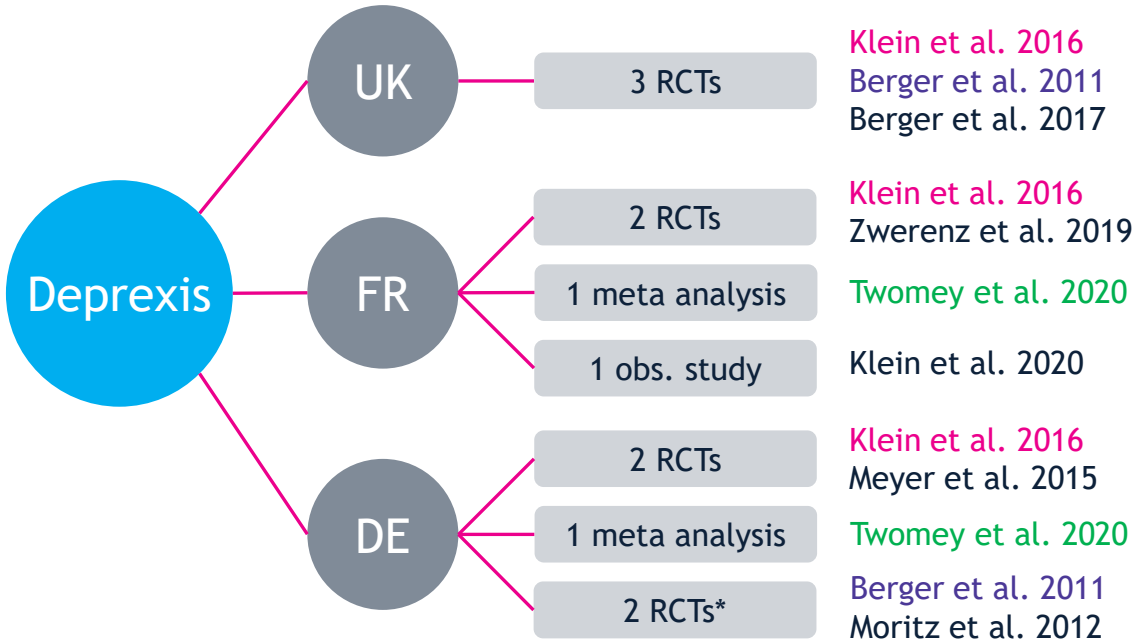
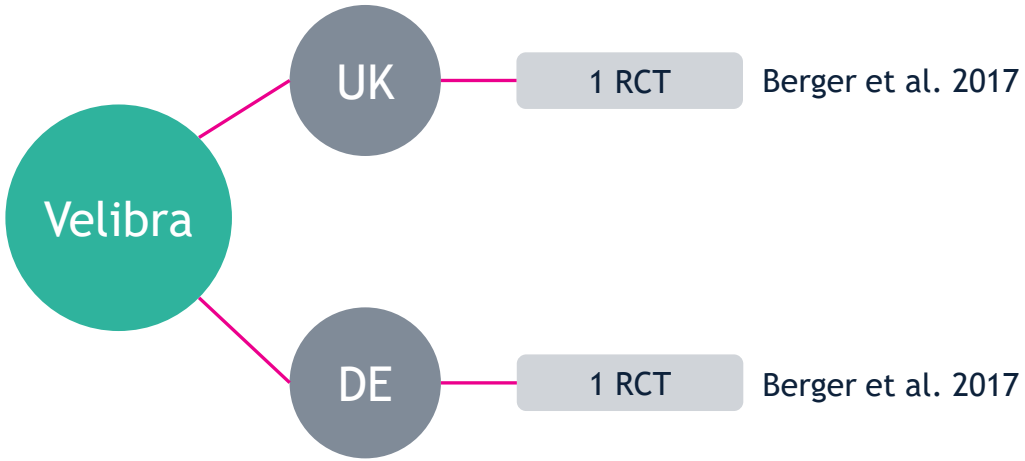
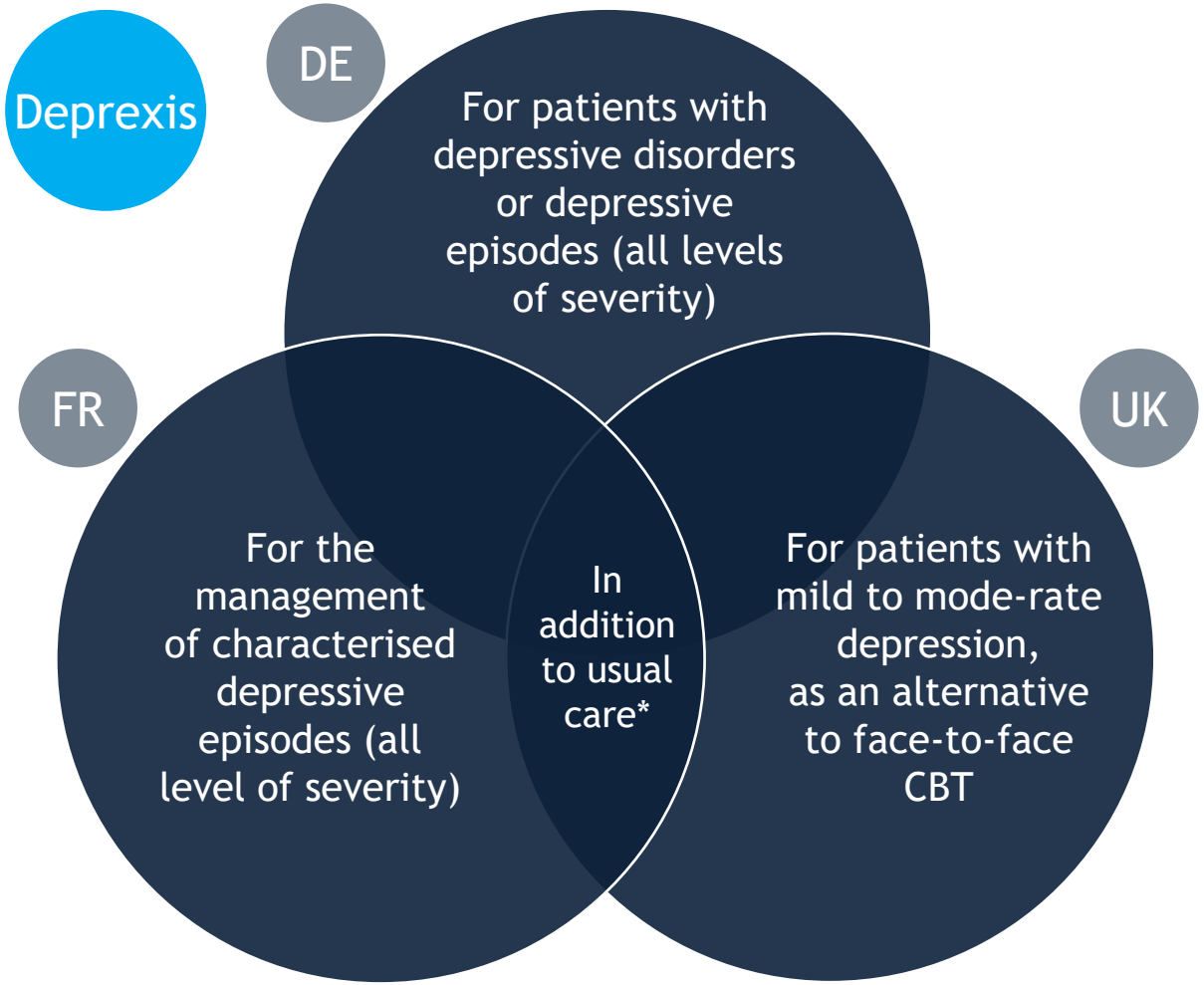
The evidence submitted is similar across countries for both DHPs

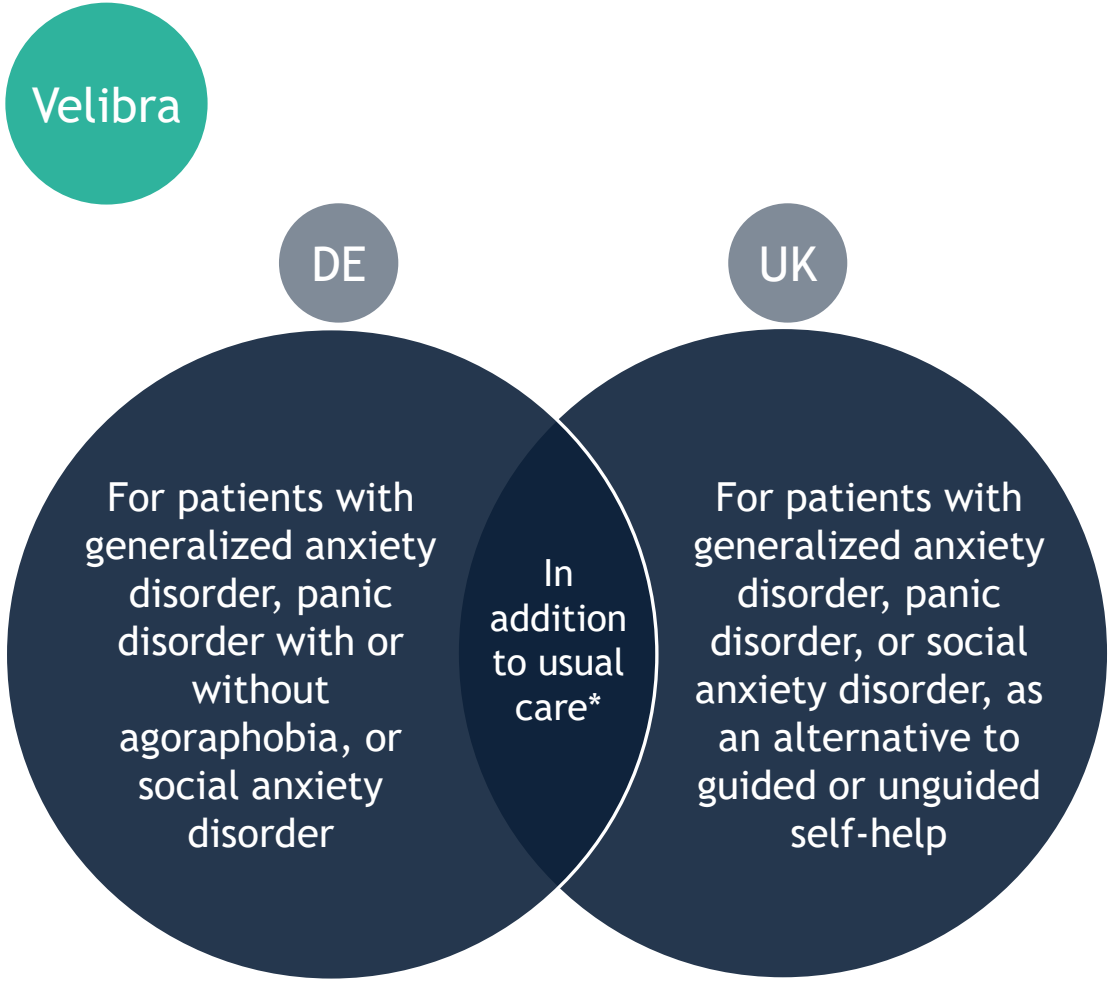




*Submitted as supplimentary evidence

Positioning of both products is **in addition to usual care** across all countries, but population characteristics slightly change across countries to fit country specific needs





*Usual care differs per country and degree of severity.

Comments from assessors on population, positioning, and comparators used

	Population		Positioning		Comparators	
	Deprexis	Velibra	Deprexis	Velibra	Deprexis	Velibra
DE	✓	✓	✓	✓	✓	✓
	-	-	-	-	-	-
UK	?	?	✓	✗	✗	?
	(Unclear if submitted by manufacturer or determined by assessors)	(Unclear if submitted by manufacturer or determined by assessors)	Not directly equivalent to fact-to-face CBT, less tailored to needs.	Without therapist guidance does not satisfy NICE guidance.	The use with psychotherapy is not representative of the care model that would be used in the NHS - limited generalizability	Patients had access to usual care, but it was not recorded so whether it affected the study results is unclear
FR	✓	NA	✓	NA	✓	NA
	Applied for all levels of severity, only accepted for mild depressive episodes	NA	For physicians to prescribe in addtition to usual care and in accordance with the patients	NA	It was highlighted that deprexis would not replace existing therapies	NA

Assessed
Not accepted
Accepted
Partially accepted
Unclear

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Comments from assessors on efficacy and safety evidence

	Efficacy		Safety	
	Deprexis	Velibra	Deprexis	Velibra
DE	✓	✓	✓	✓
	Deprexis can effectively reduce the symptoms of depression	Velibra effectively reduces various forms of anxiety disorders in addition to general practitioner treatment	Requirements fulfilled *(risk-flagging system integrated)*	Requirements fulfilled *(risk-flagging system integrated)*
UK	✓	✗	✓	✗
	Outcome measures were relevant for the NHS. Studies well designed, but potentially affected by selection bias (internet forum recruitment)	Study not adequately powered. Panel critised the assessment of 3 indications in one study. Approach not in line with NICE guidance	Issues in manual were noted: - Only response to risk of suicidality outlined, not to self-harm. - Manual needs adaptation or referall to local protocols	No risk-flagging capacity, there were no triggers to identify when patient safety becomes a concern
FR	✓	-	✗	-
	Moderate improvements only for patients with mild to moderate depressive disorders. Systematic diagnosis by a HCP was missing/difficult to interpret. French study with real-life data requested for re-assessment	NA	Safety outcomes in real life are missing. Adverse events were described in the only observational study. To be investigated in the re-assessment (5-years)	NA

Assessed
Not accepted
Accepted
Partially accepted
? Unclear

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Comments from assessors on unmet need, usability, and economic evidence

	Unmet need		Usability		Economic outcomes	
	Deprexis	Velibra	Deprexis	Velibra	Deprexis	Velibra
DE	🔍?	🔍?	🔍✓	🔍✓	NA	NA
	-	-	Requirements fulfilled	Requirements fulfilled	NA	NA
UK	🔍✓	🔍?	🔍✓	🔍✓	🔍?	🔍?
	Multiple languages available and may facilitate access for hard-to-reach populations. However, in a therapist-guided care model, the therapist would need to speak the same language as the user	-	There is some tailoring of content to the user's needs. The domains of usability and accessibility were acceptable to the technical assessors	Limited tailoring of content to user needs. Lengthy technology, potentially difficult for some users to follow. Overall, the standard were acceptable, but there was room for improvement	Unlikely to deliver cash releasing savings, but potentially increases access to care as therapists might be able to treat more patients at a lower cost. No UK specific cost data available*	Unlikely to deliver cash releasing savings, but it may free staff time to deal with more dependent people. Potential positive impact on resource use*
FR	🔍✓	NA	🔍✓	NA	🔍✗	NA
	Deprexis responds to the need of accessible healthcare (waiting times, geographical distance, etc.)	NA	Data related to the patient's engagement with the software will be investigated in the re-assessment	NA	No evidence submitted. No organizational impact is demonstrated*	NA

🔍 Assessed
✗ Not accepted
✓ Accepted
✓ Partially accepted
? Unclear

*No published evidence submitted

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Final considerations from the analysis of assessments

- Heavy focus on positioning of product and comparators from authorities based on clinical evidence, usability, & impact (particularly France and the UK)
- Essential to contextualize the product to country specific care models and through country specific real-word data and consensus/awareness research
- High focus on usability in the UK, relevant also Germany and structured in both assessment frameworks, France seems to focuse more on usage data.
- Safety data: Risk-flagging system relevant in Germany and the UK, France focuses more on adverse events associated with the products.
- In UK and France, authorities seem to focus on the added social value (e.g. increased access) that DHPs products bring

Essential evidence:

1. Efficacy

- **High-quality clinical evidence requested**: RTCs in line with context specific clinical guidelines + SLRs and Meta-analyses
  - Relevant for efficacy data to **fit to local system's requirements** (e.g., positioning, comparators, RWE, etc.).

2. Usability & impact

- **Digital data on usability/usage**: usability research (pre) or usage data (post) requested
- **Unmet need and impact**: assessment of patients' and system's needs (consensus research beneficial)
- **Economic evidence**: needed only in the UK (in France only if budget impact is significant)

3. Safety

- **Adverse Events** data still relevant (particularly in France), in Germany and the UK there is a stronger focus on **risk-flagging systems.**

What the future holds for us?

- Establishing a **single HTA framework at EU level** (if not even reimbursement practices) in line with the new HTA regulation.

- Expanding the role of **DHPs in the HTA of other health and healthcare innovations** and initiatives (pharma, medical devices, policies, etc.)
  - Launch and Implementation of digital companions - the EU pharma strategy lays out incentives, but we are not there yet!
  - Full integration of DHPs data into broader data spaces (such as the European health data space)

- Expanding **investments on data driven prevention** –public and private investments in DHPs that demonstrate efficacy on preventing

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Any questions?

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Thank you for you attention!

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