# Stakeholders' perspectives on real-world evidence generation
## Healthcare professional

Joint HMA/EMA multi-stakeholder workshop on Patient Registries for Alzheimer's disease
15th of December 2025

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DANISH DEMENTIA RESEARCH CENTRE

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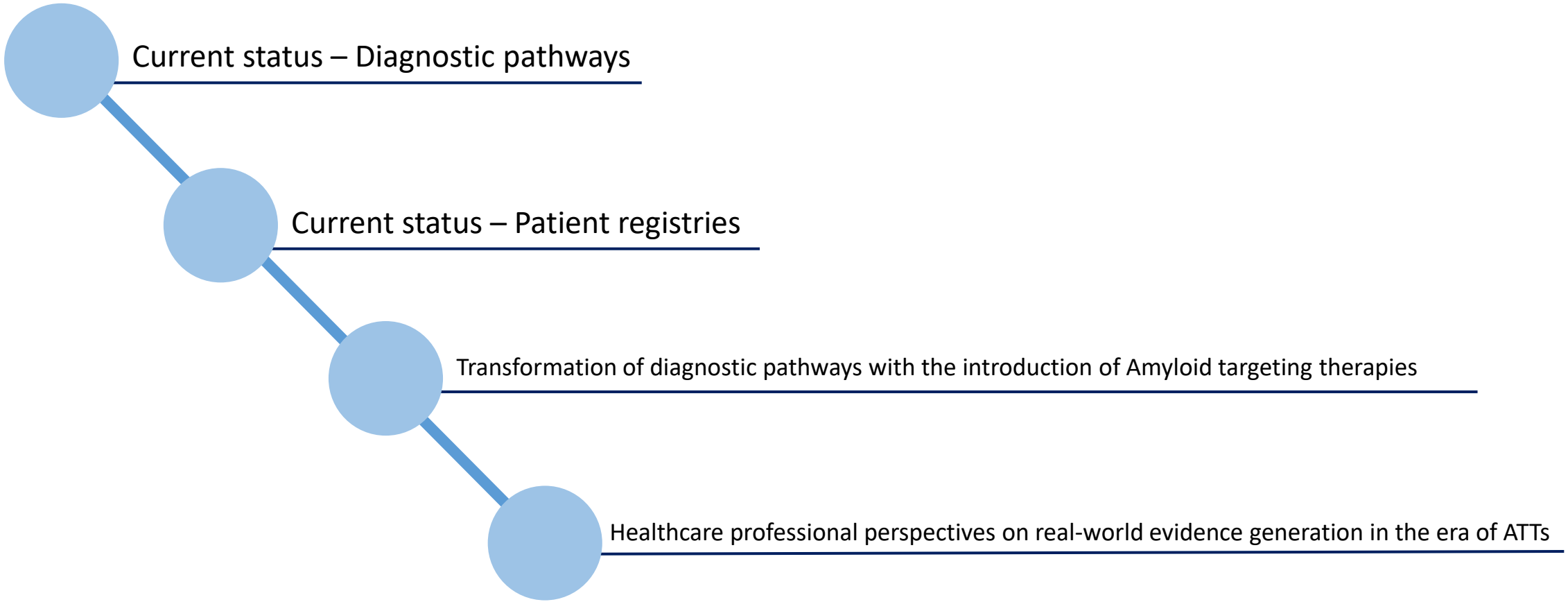


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# Current status – Diagnostic pathways

NATIONALT VIDENSCENTER FOR DEMENS

Patients with undiagnosed Alzheimer`s disease

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# Current status – Diagnostic pathways

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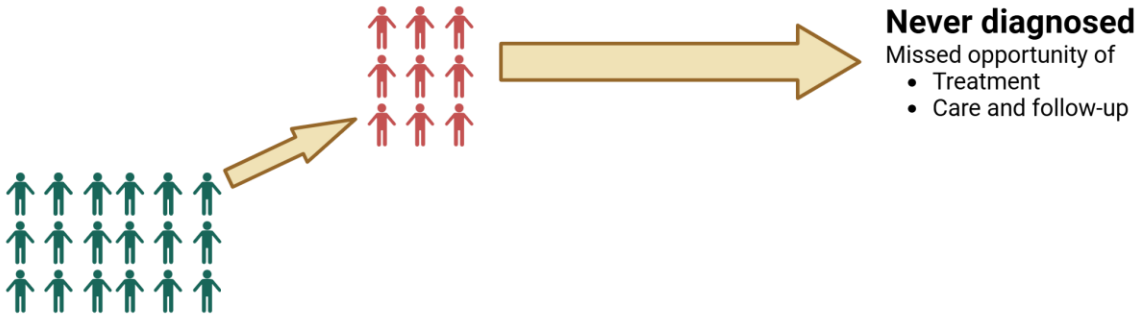

**Never diagnosed**

Missed opportunity of

- Treatment
- Care and follow-up

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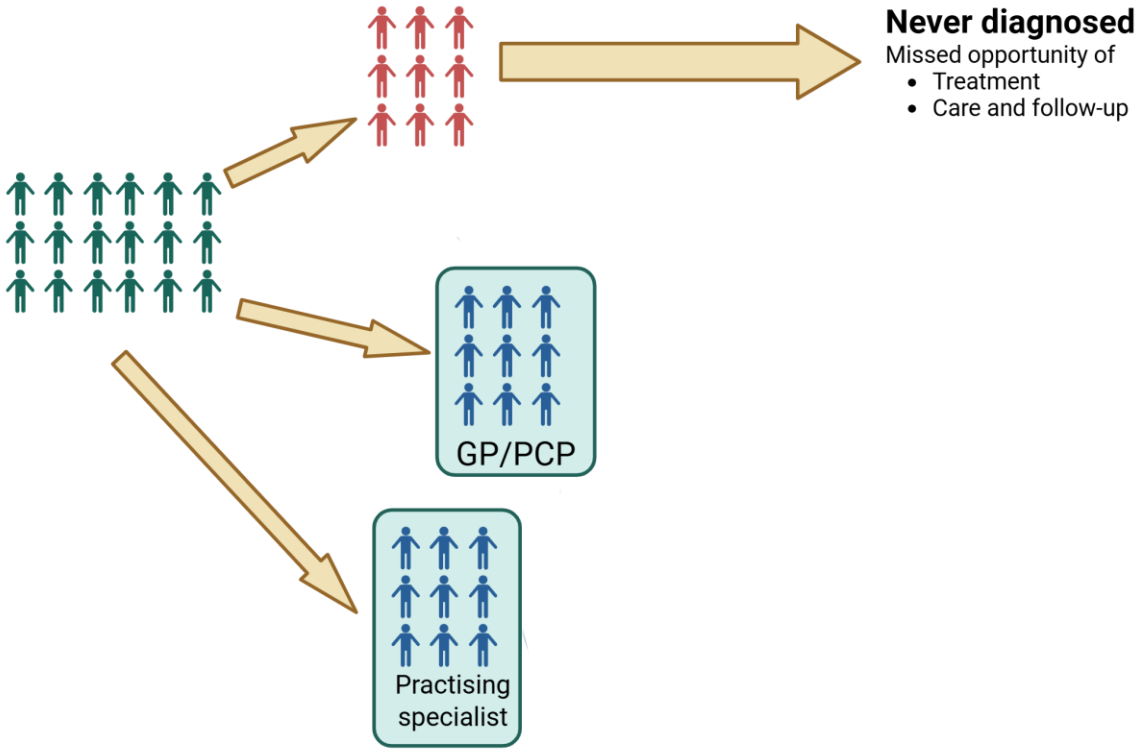
# Current status – Diagnostic pathways

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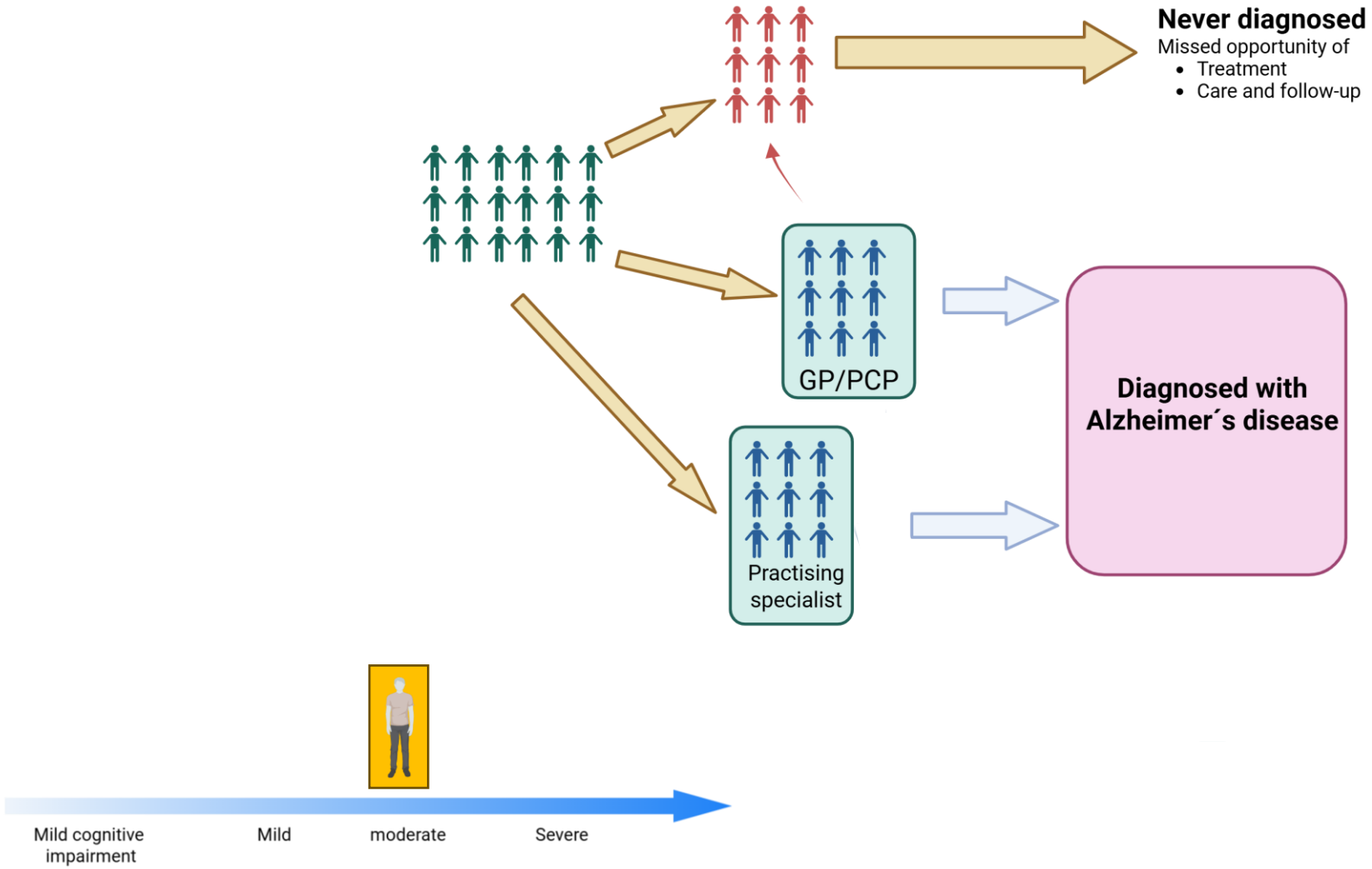
# Current status – Diagnostic pathways

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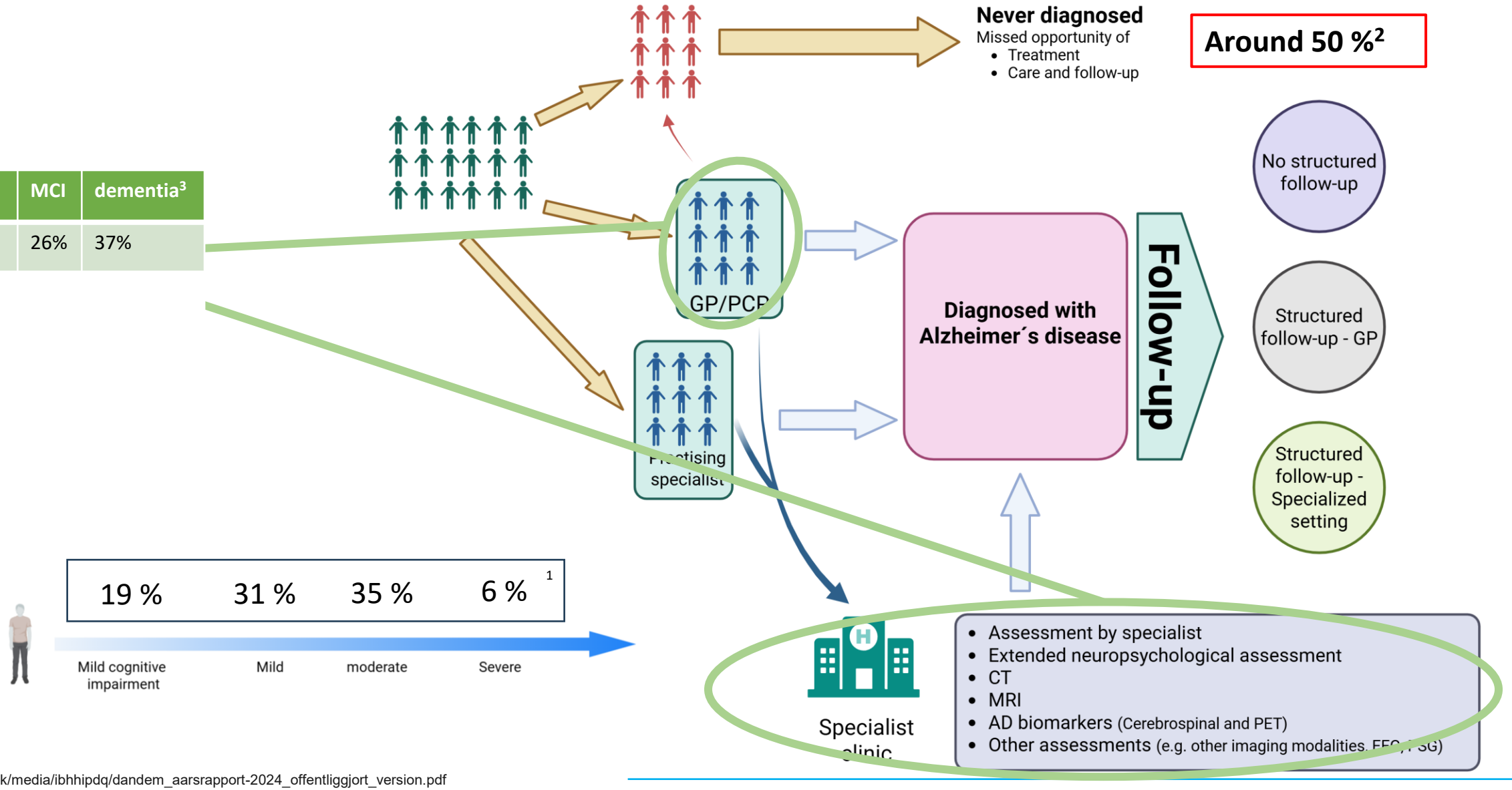
# Current status – Diagnostic pathways

NATIONALT VIDENSCENTER FOR DEMENS

| | MCI | dementia[3] |
|---|---|---|
| Primary | 26% | 37% |




[1]https://www.sundk.dk/media/ibhhipdq/dandem_aarsrapport-2024_offentliggjort_version.pdf
[2]Lang L, et al. Prevalence and determinants of undetected dementia in the community: a systematic literature review and a meta-analysis. BMJ Open. 2017 Feb 3;7(2):e011146
[3]https://www.ucr.uu.se/svedem/resultat/arsrapporter/arsrapporter/svedem-arsrapport-2024
Frederiksen KS, et al. Biomarker counseling, disclosure of diagnosis and follow-up in patients with mild cognitive impairment: A European Alzheimer's disease consortium survey. Int J Geriatr Psychiatry. 2021 Feb;36(2):324-333.

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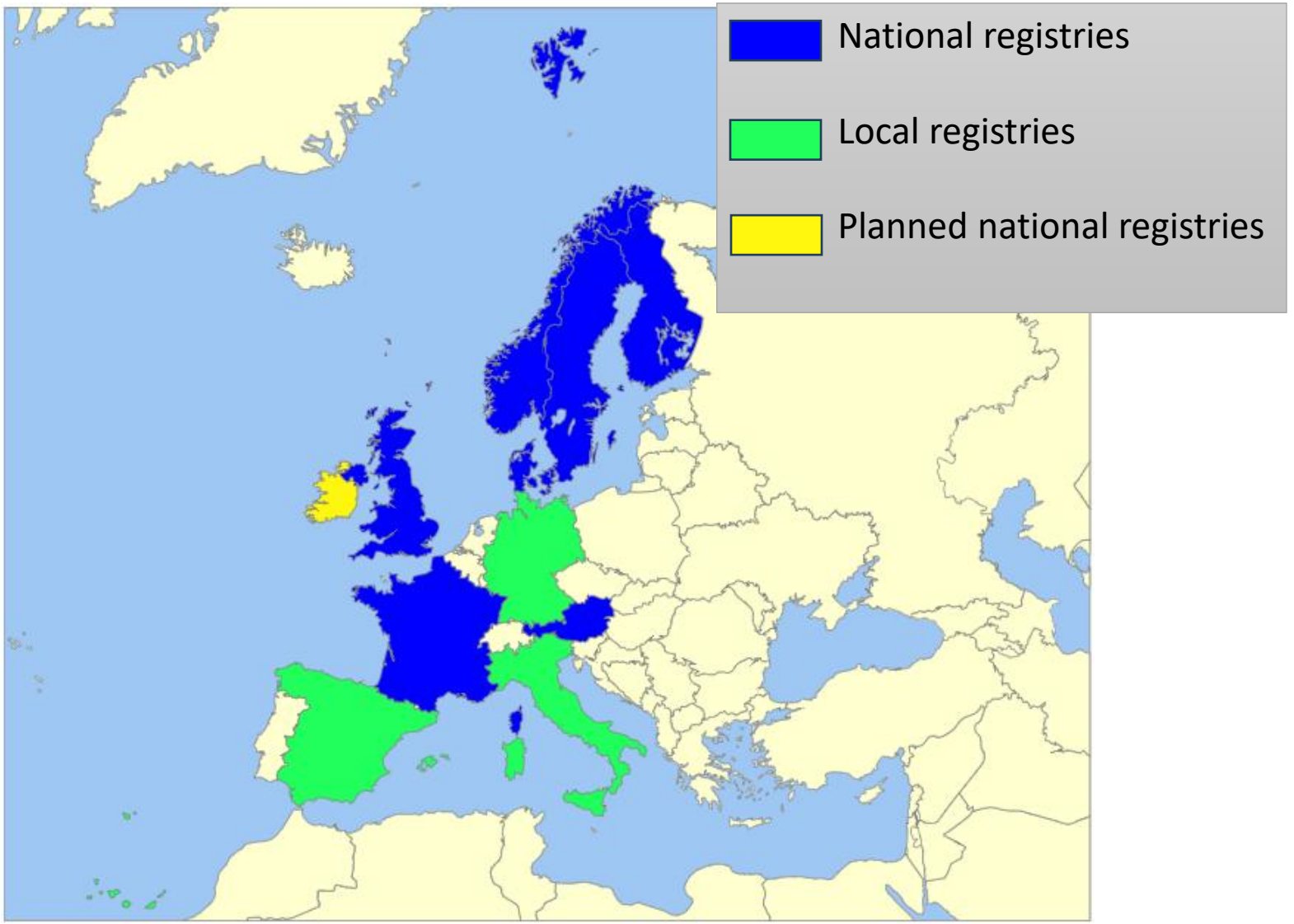
# Current status – Patient registries

- No pan-European registry
- Few national registries
- Variable coverage and setting
  - Dementia
  - Dementia+MCI
  - Epidemiology vs. Quality of care
  - Cross-sectional vs. longitudinal




Garland H, Jacobson M, Xu S, Zissimopoulos J. A scoping review of population-based dementia registries: advancing research, care, and policy. *Alzheimer's Dement*. 2025; 21:e70938
https://www.noca.ie/audits/irish-dementia-registry/?utm_source=chatgpt.com
https://www.sundk.dk/kliniske-kvalitetsdatabaser/dansk-klinisk-kvalitetsdatabase-for-demens-dandem/

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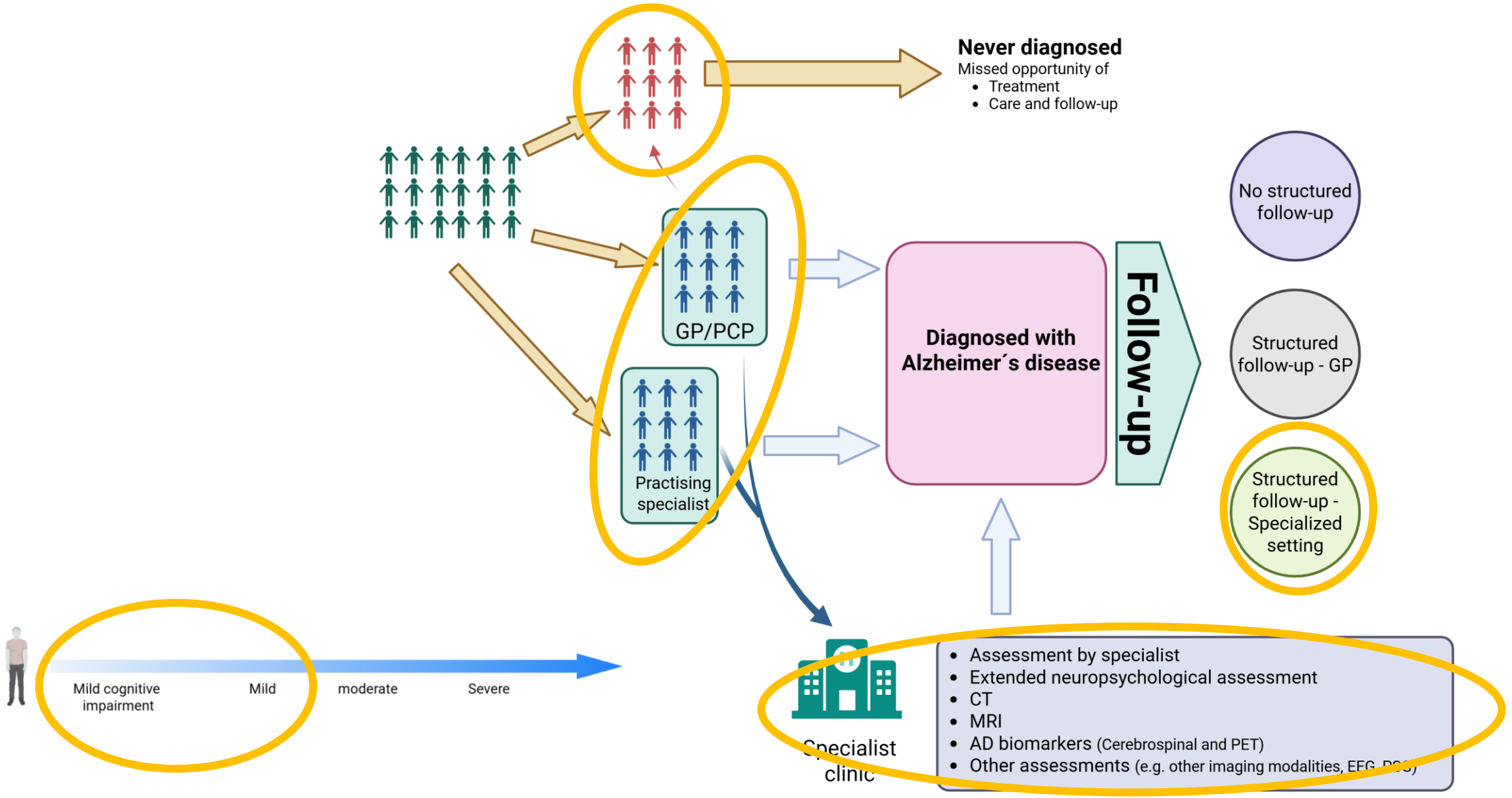
# Transformation of Diagnostic pathways with ATTs

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# Healthcare professional perspectives on real-world evidence generation in the era of ATTs

NATIONALT VIDENSCENTER FOR DEMENS

**Prerequisite for treatment and RWE generation**

- Case finding at the level of primary care
- Precise triaging to specialised center for those possibly eligible for treatment
- Increased capacity for diagnosis and follow-up in specialised centers

**Coverage**

- Need to have: All patients on anti-amyloid therapies (and considered for anti-amyloid therapies)
- Nice to have: All patients evaluated for cognitive impairment

**Outcome measures of effectiveness and safety**

- Capturing only outcomes that are relevant to anti-amyloid therapies
- Minimum of data points to ensure feasibility and coverage of registry
  - Assessment tools that are minimally time consuming
- Compliant with the SmPC

**Role of funders**

- Industry versus public funder
- Ensure independence, sustainability and data protection

**Others**

- Implementation of automation were possible (e.g automatic data capture from electronic patient charts)
- Avoid redundant data capture (e.g. in cases with more than one registry
- European Health data space

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