

## INTRODUCTION

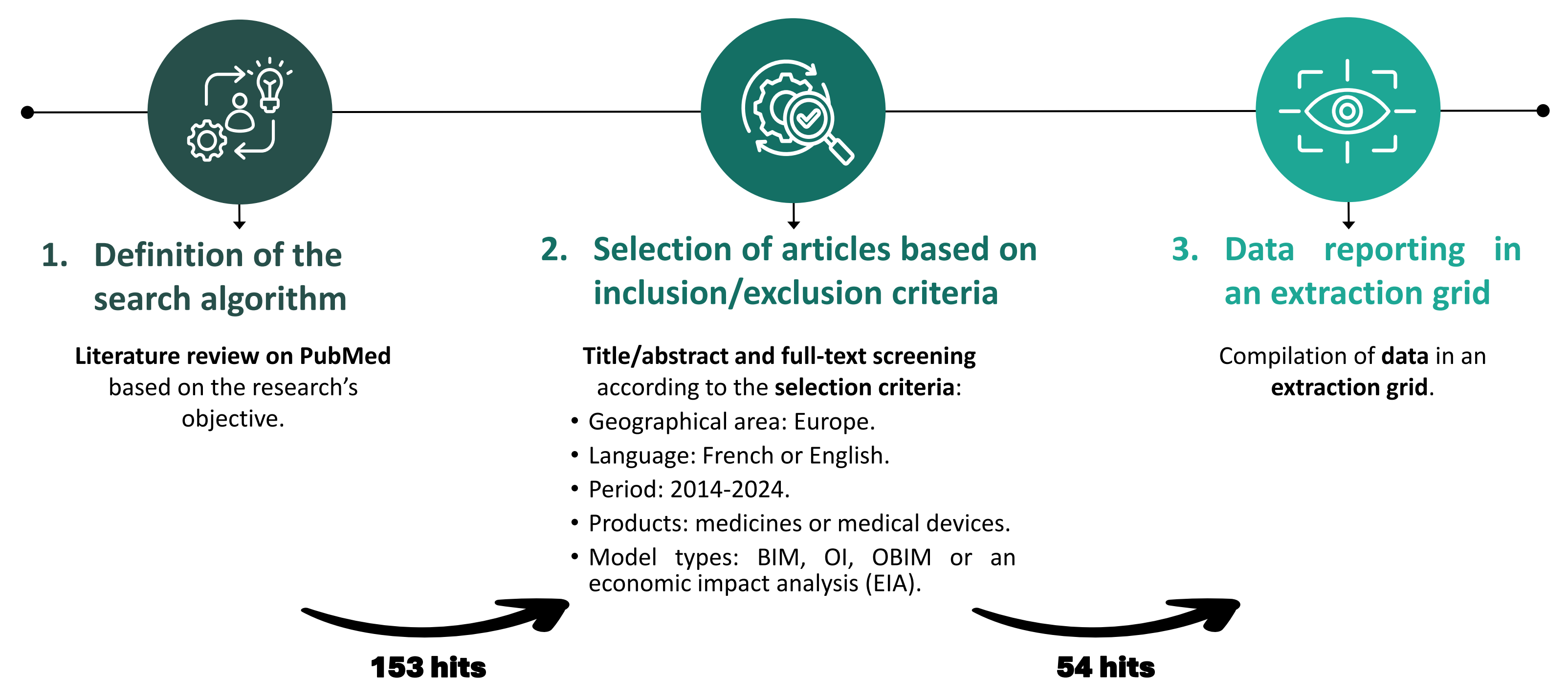
When introduced, some medical products may impact both the healthcare organization and its broader environment. Like clinical and medico-economic factors, these impacts on the organization can help differentiate healthcare products and highlight their added value.

In this context, the French National Authority for Health (HAS) published a methodological guide on budget impact analysis (BIM) in 2016<sup>1</sup> and a guide on organizational impacts (OI) in 2020.<sup>2</sup>

With these advances, a new type of modeling has emerged over the past few years, combining OI and BIM, termed organizational and budget impact models (OBIM).

The aim of this study was to provide an overview of the types of impact studies conducted in Europe for the last decade.

## METHOD



## RESULTS

A total of 54 publications were selected. Of these, 83% (n=45) focused on both BIM and EIA, 13% (n=7) presented an OBIM, and 4% (n=2) centered on an OI model only (*figure 1*). Among the included studies, 87% (n=47) performed an impact study on a medicine, while 13% (n=7) focused on a medical device (*figure 2*).

Hematology-oncology (n=11), rheumatology-immunology (n=10), gastroenterology (n=7), and infectiology (n=7) were the primary therapeutic indications examined in these impact studies. A small number of relevant papers focused on multiple disease areas in their analyses (n=3) (*figure 3*).

Figure 1. Number of articles per type of impact study

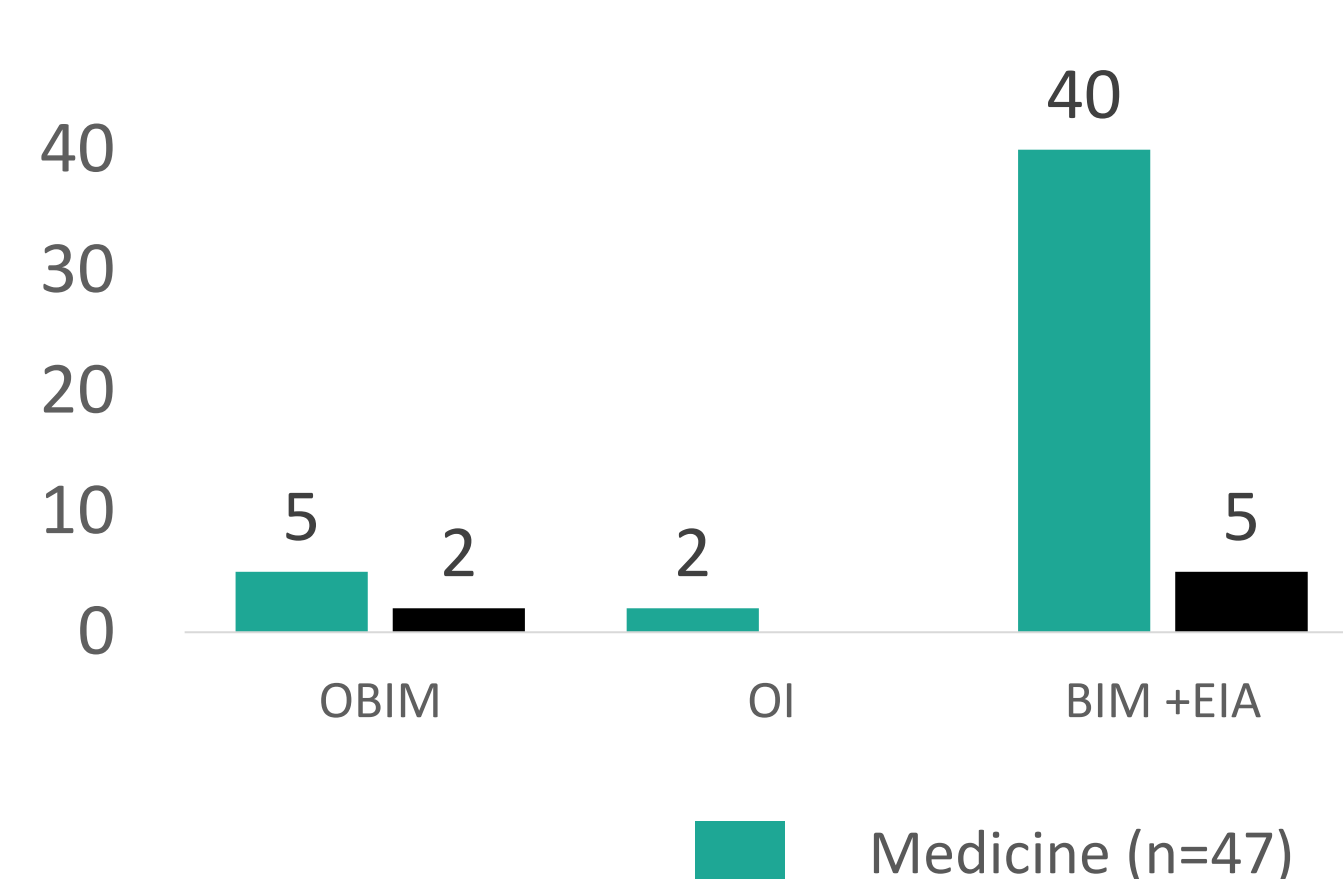


Figure 2. Study repartition, per type of medical product

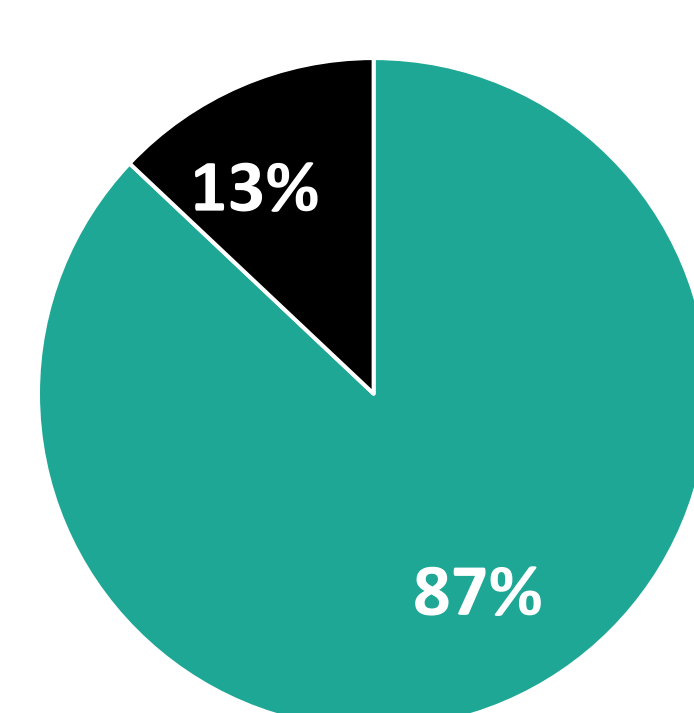
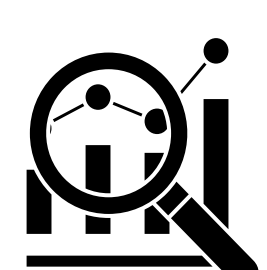
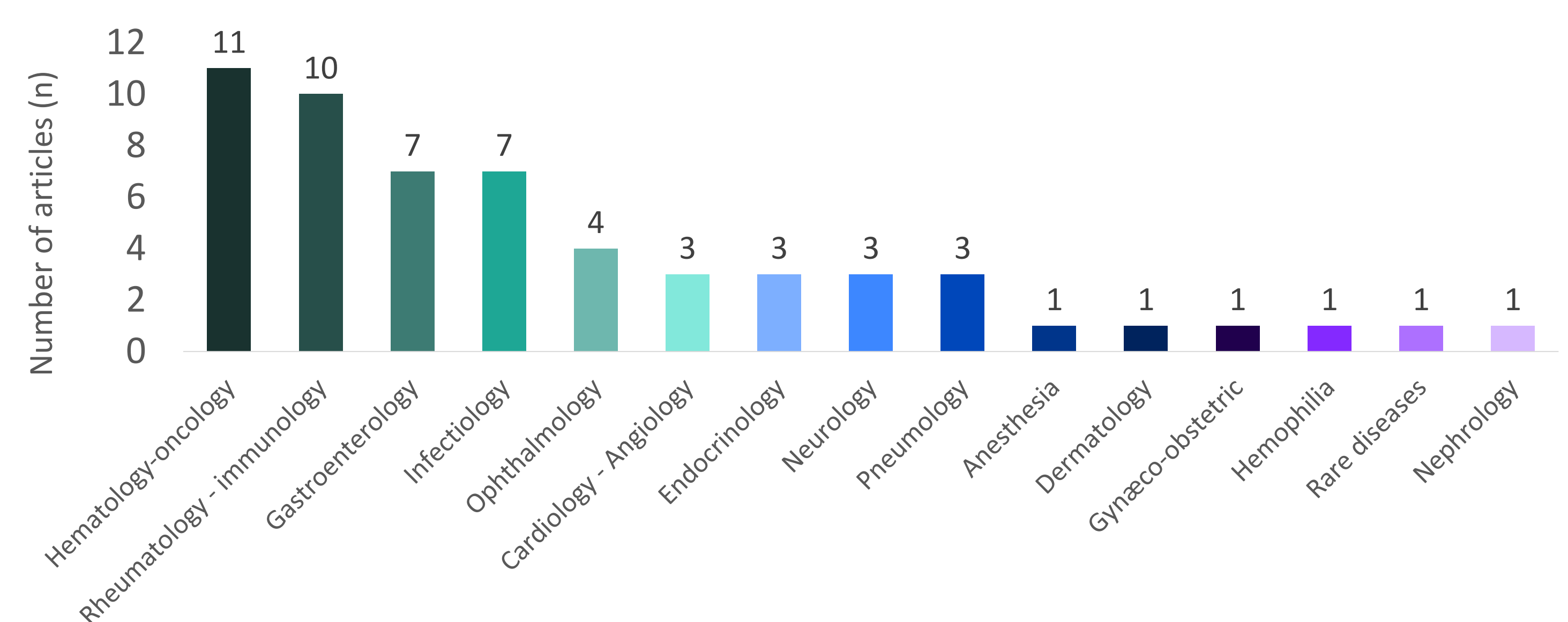


Figure 3. Number of articles, per disease area



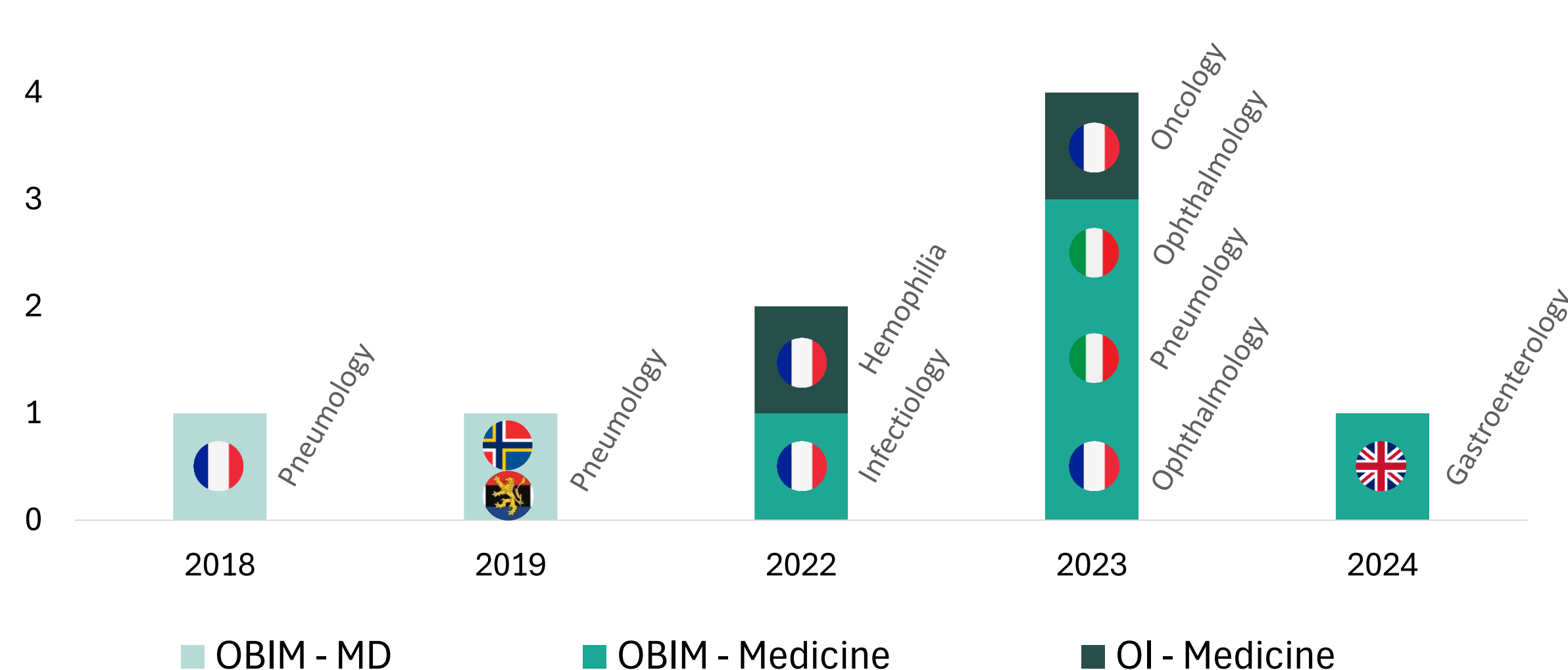
### Focus on OI and OBIM

Among all OI and OBIM studies (n=9), more than half were conducted in France (n=5, 56%). Medical devices were observed to be the first type of medical product explored, when OBIM studies emerged in 2018, but medicines appeared to be more commonly studied using both OI and OBIM approaches in the past two years. It was also noticed that pneumology and ophthalmology were the primary disease areas investigated, in 33% (n=3) and 22% (n=2) of cases, respectively (*figure 4*).

Several criteria, used to estimate impacts on multiple dimension in the context of OI and OBIM studies, were identified through studies of interest (*table 1*).

The impact criteria used in both OBIM and OI models were strongly concerned with the consumption of hospital resources and, for several of them, focused on unscheduled hospitalization.

Figure 4. Number, disease areas and geographical scope of OI and OBIM studies identified, pear year (n=9)



The question of the organizational impacts on healthcare professionals was mainly explored in the French OI models and OBIM. Among the nine OI and OBIM studies, 33% (n=3) focused on this type of impact criteria and were all conducted in France (n=2 OI and n=1 OBIM).

Environmental impacts are still rarely explored in this type of model developed to evaluate healthcare products. In this literature review, only one OI study conducted in the Nordics and Benelux on a pneumology medical device included an environmental impact criterion.

Table 1. Main organizational outcomes criteria identified through OI/OBIM studies

Organizational Impact Criteria	
<b><u>Impact on healthcare management:</u></b> <ul style="list-style-type: none"> <li>Hospital bed occupancy/patient flow</li> <li>Medical time</li> <li>Hospital length of stay reduction</li> <li>Number of ER visits</li> <li>Number of non-scheduled medical visits</li> <li>Re-operations</li> <li>Surgical failures</li> <li>Change in healthcare management</li> <li>Infrastructure (surfaces occupied, maintenance and certification)</li> <li>Supply (product, associated devices)</li> <li>Vigilance and monitoring methods (traceability, pharmacovigilance and compliance in use and processing)</li> </ul>	<b><u>Impact on actors:</u></b> <ul style="list-style-type: none"> <li>Number of pathway and interface actors</li> <li>Medical and non-medical personnel training</li> <li>Working conditions</li> <li>Safety</li> <li>Acceptability for patients / caregivers / association (efficacy, tolerance, practicality, adherence)</li> <li>Accessibility</li> <li>Type and level of involvement of the patient / carer</li> <li>Cooperation and communication modes</li> <li>Change in patients' recruitment for CT</li> </ul>
	<b><u>Impact on society:</u></b> <ul style="list-style-type: none"> <li>Environmental impacts reduction</li> <li>Complexity of innovation and informed choice</li> </ul>

Abbreviations: CT: Clinical trial ; ER: Emergency room.

## CONCLUSION

Based on study outcomes, it appears that the first OI models and OBIM have emerged recently, initially focusing on medical devices. Nevertheless, these impact studies have increasingly extended to include medicines over the past years.

Despite expectations from national and local authorities regarding the demonstration of the impact of healthcare products within the value-based healthcare framework, OI models and OBIM remain underdeveloped and rarely or unequally published in Europe.

## REFERENCES

<sup>1</sup> HAS (2016) – *Choix méthodologiques pour l'analyse de l'impact budgétaire à la HAS*

<sup>2</sup> HAS (2020) – *Cartographie des impacts organisationnels pour l'évaluation des technologies de santé*