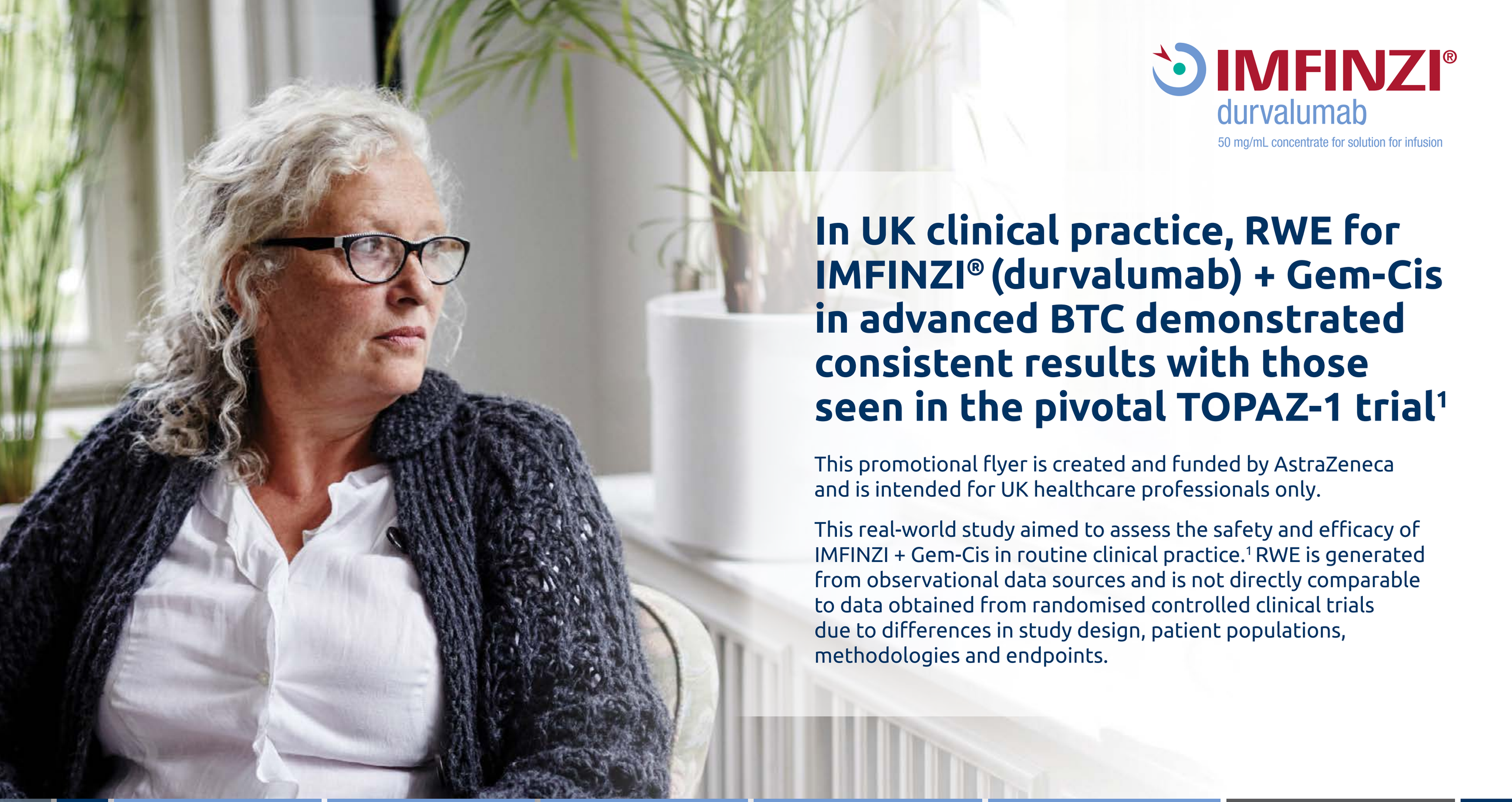

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durvalumab
50 mg/mL concentrate for solution for infusion

In UK clinical practice, RWE for IMFINZI® (durvalumab) + Gem-Cis in advanced BTC demonstrated consistent results with those seen in the pivotal TOPAZ-1 trial[1]

This promotional flyer is created and funded by AstraZeneca and is intended for UK healthcare professionals only.

This real-world study aimed to assess the safety and efficacy of IMFINZI + Gem-Cis in routine clinical practice.[1] RWE is generated from observational data sources and is not directly comparable to data obtained from randomised controlled clinical trials due to differences in study design, patient populations, methodologies and endpoints.

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The real-world study ran at 10 centres across the UK, with results broadly consistent with those from the TOPAZ-1 trial* and other multicentre real-world studies.[1]

Click here to view all the centres

*TOPAZ-1 was a double-blind, placebo-controlled, Phase III study, in which patients (n=685) with previously untreated, unresectable or metastatic BTC or with recurrent disease 1:1 were randomly assigned to receive IMFINZI or placebo in combination with Gem-Cis, followed by IMFINZI or placebo monotherapy. The primary endpoint was OS, and secondary endpoints included PFS, ORR and safety.[2]

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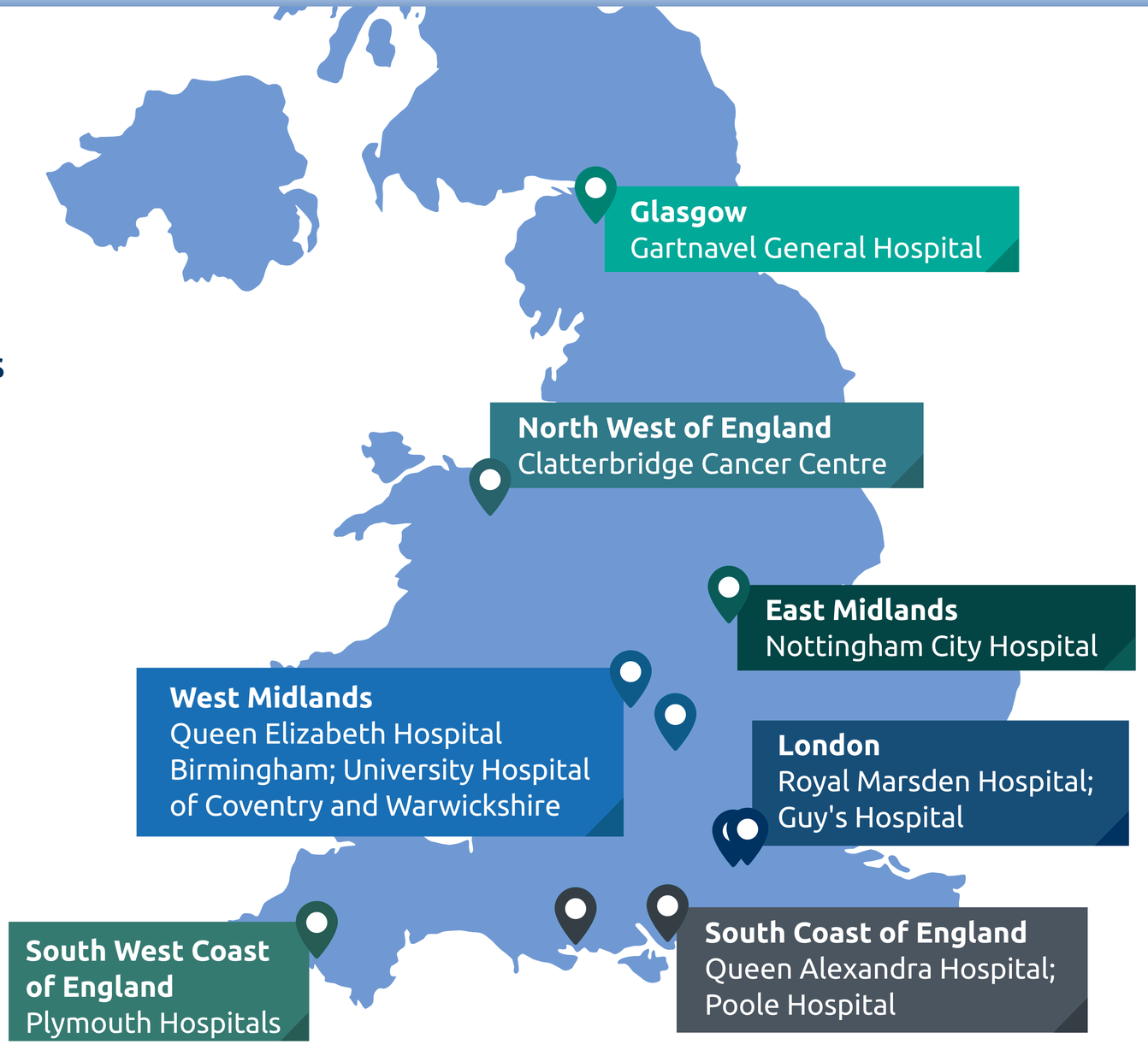

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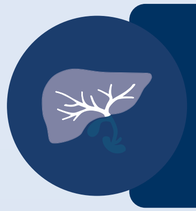
Demographic data of patients

A total of **134 patients** with advanced, unresectable or metastatic BTC received this combination therapy via the real-world study. The primary endpoint was PFS, and the secondary endpoints included OS, ORR and safety outcomes.[1]



Intrahepatic

➤ View ECOG PS

Extrahepatic

➤ View ECOG PS

Gallbladder

➤ View ECOG PS

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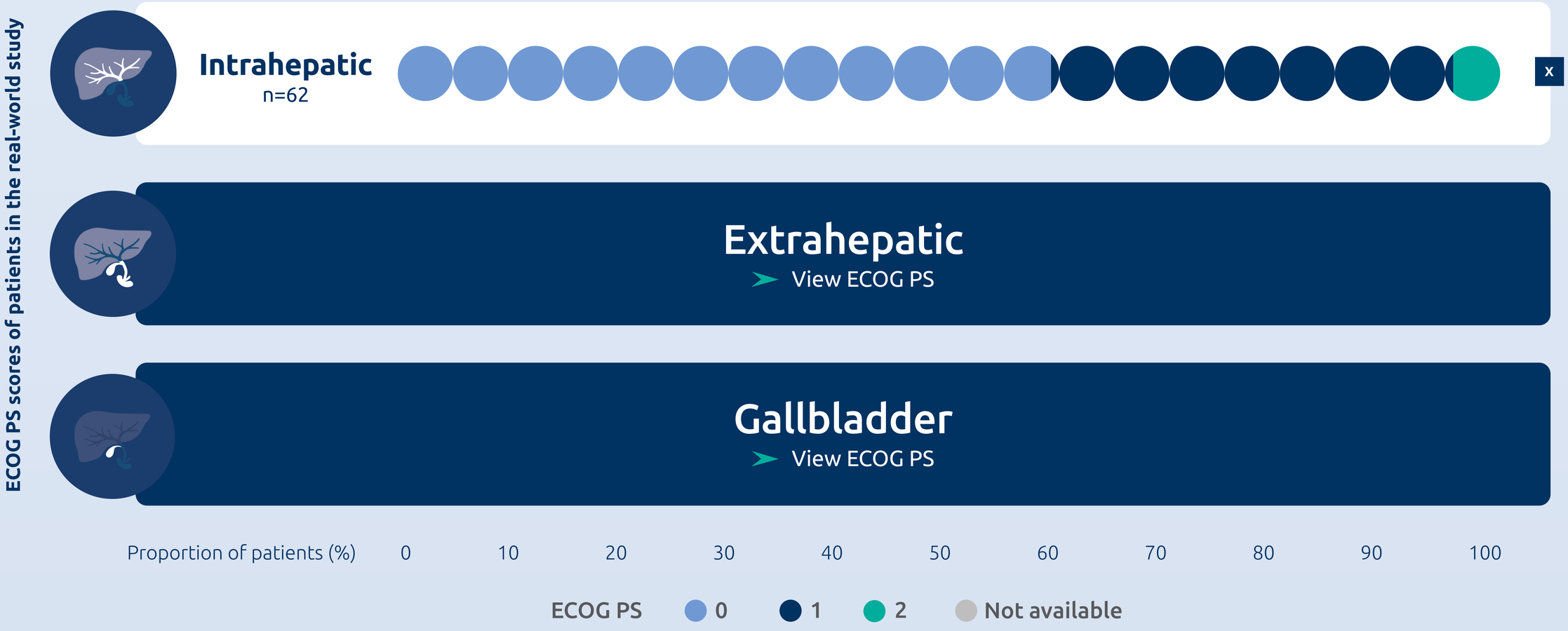

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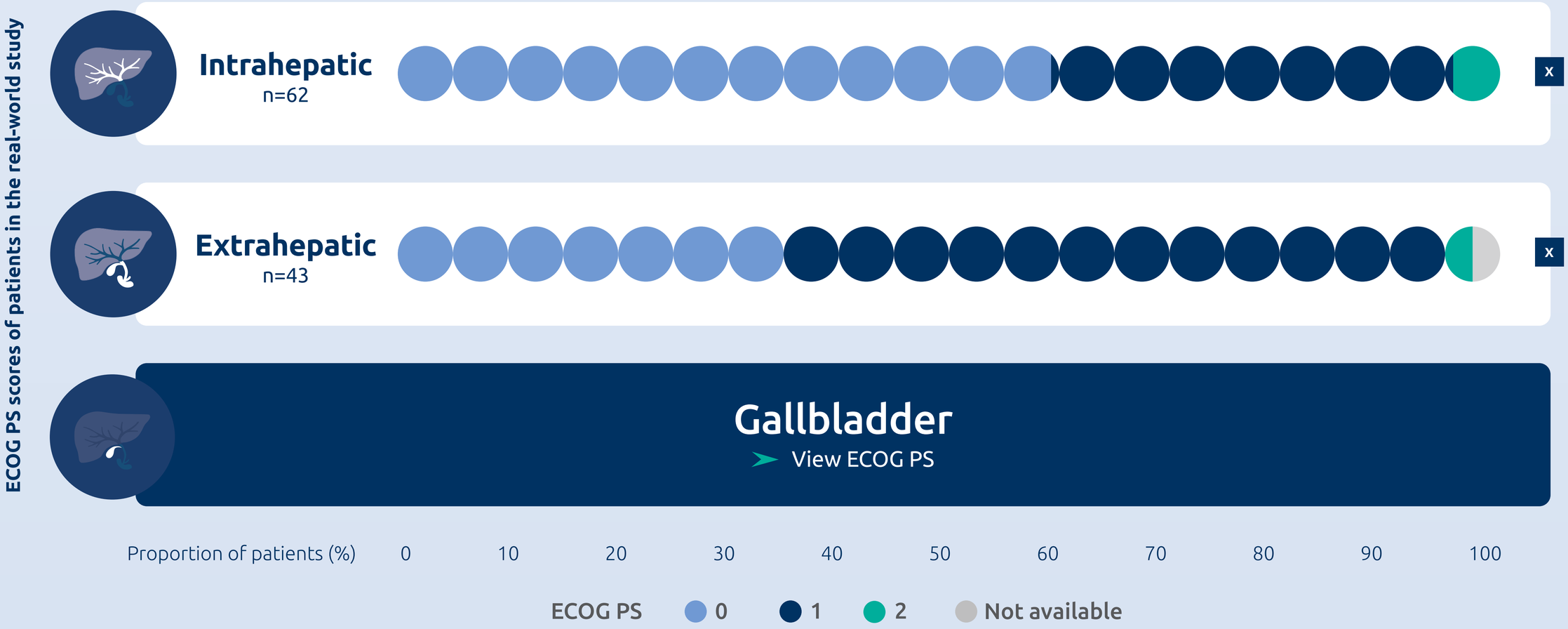

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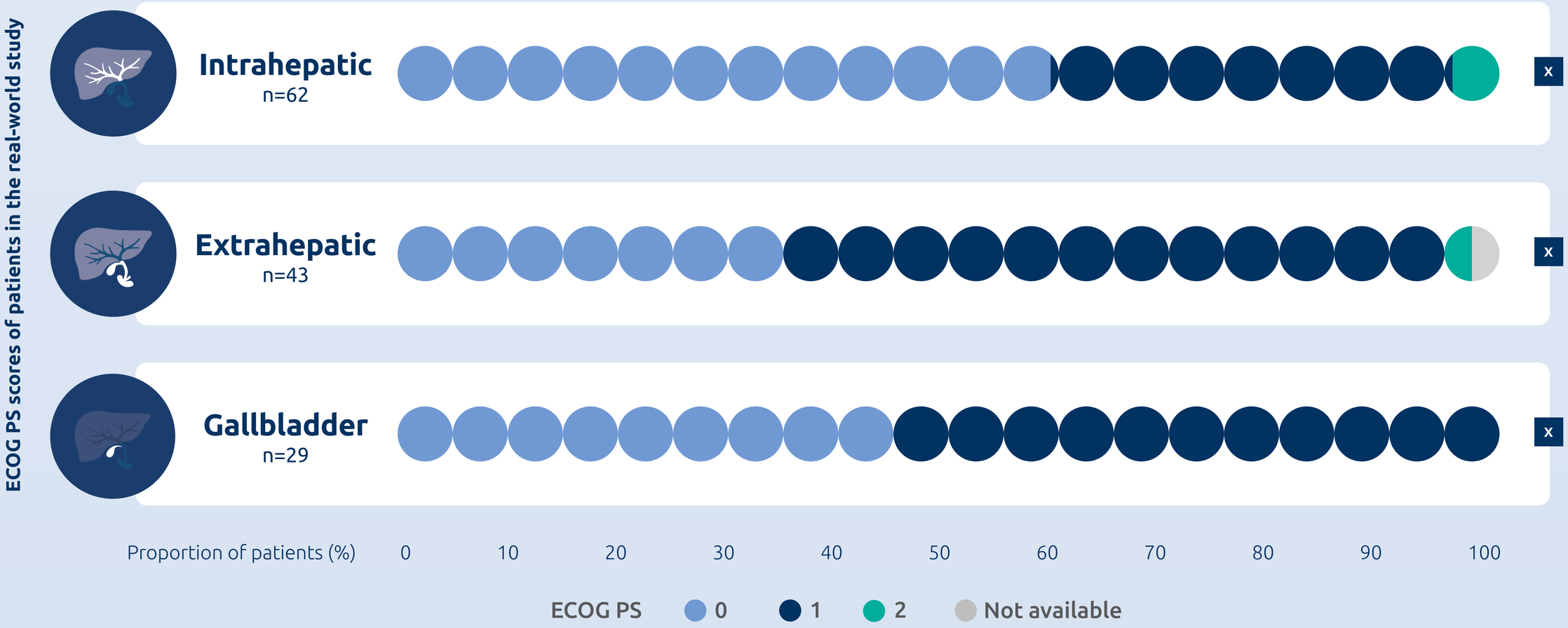

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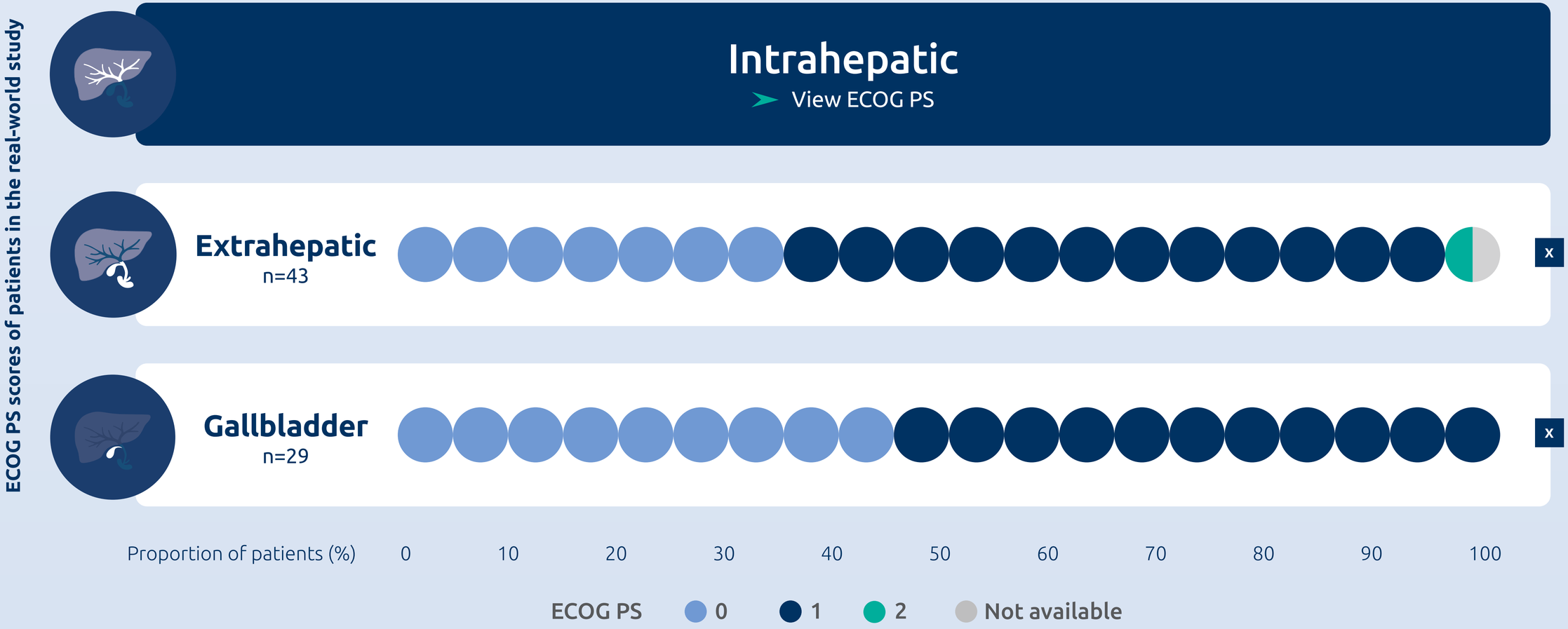

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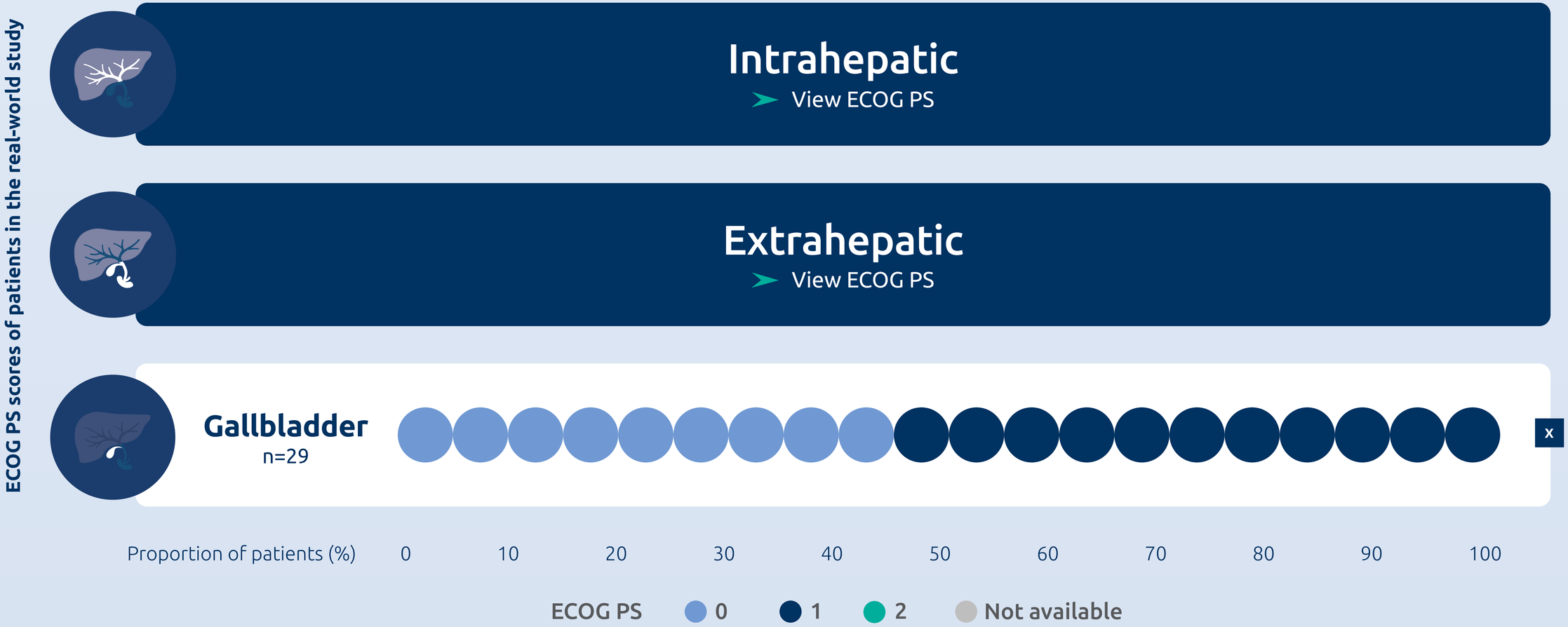

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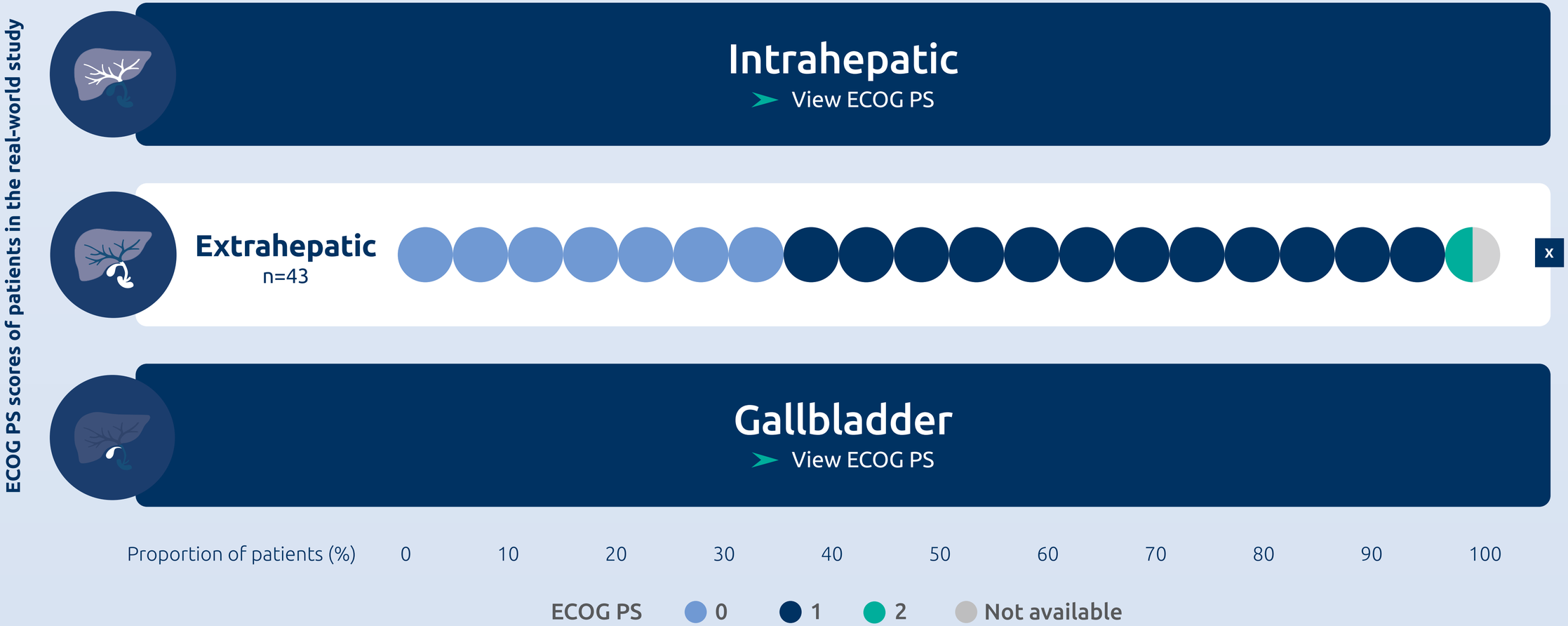

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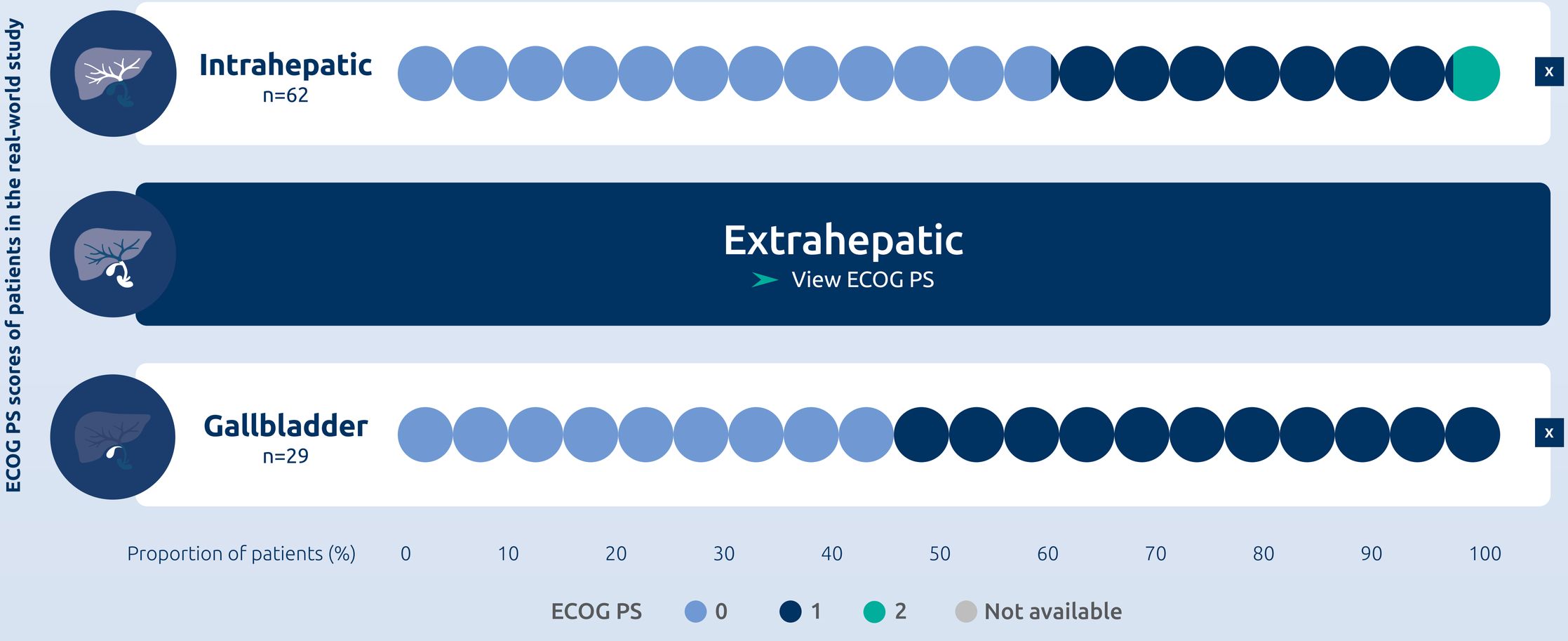

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Safety profile of IMFINZI + Gem-Cis

IMFINZI + Gem-Cis was well tolerated in real-world UK practice, consistent with the TOPAZ-1 trial.[1,2]

Safety profile of IMFINZI + Gem-Cis in the RWE population		
Any AEs	Any Grade	64 (52.3%)
	Grade 3–4	9 (6.8%)
Immunotherapy-related AEs	Any Grade	25 (18.7%)
	Grade 3–4	4 (3.0%)
Chemotherapy-related toxicity	Any Grade	60 (44.7%)

The most common (>20%) adverse reactions in patients treated with IMFINZI in combination with chemotherapy (based on pooled data from five studies) were neutropenia, anaemia, nausea, fatigue, constipation, decreased appetite, thrombocytopenia and rash. Please refer to the SmPC for more information on AEs.[3]

Efficacy of IMFINZI + Gem-Cis

Efficacy of outcomes observed in the real-world study were consistent with those reported in the TOPAZ-1 trial, reinforcing the real-world applicability of the TOPAZ-1 trial data.[1,2]

mPFS:[1]

Read more

mOS:[1]

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x

mPFS:[1] **8.33 months**

mOS:[1]

Read more

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mPFS:[1]

Read more

x

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mPFS:[1] **8.33 months**

mOS:[1] **12.0 months**

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Duration of treatment

In the UK, IMFINZI + Gem-Cis is indicated for the 1L treatment of adults with locally advanced, unresectable, or metastatic BTC.[3] The regimen includes IMFINZI 1500 mg (D1) + gemcitabine 1000 mg/m² and cisplatin 25 mg/m² (each D1 & D8) Q3W for up to 8 cycles, followed by IMFINZI 1500 mg Q4W for as long as clinical benefit is observed or until unacceptable toxicity.[†2,3]

[†]Patients with body weight ≤36 kg must receive IMFINZI 20 mg/kg Q3W with chemotherapy, then 20 mg/kg Q4W as monotherapy, until weight >36 kg. Please refer for the SmPC for full details on licensed posology.[3]

Click here to see duration of treatment in real-world study

The results from the UK RWE for IMFINZI + Gem-Cis demonstrated outcomes broadly consistent with the TOPAZ-1 clinical trial, highlighting the potential benefit of adding Gem-Cis to IMFINZI in the real-world setting.[1]

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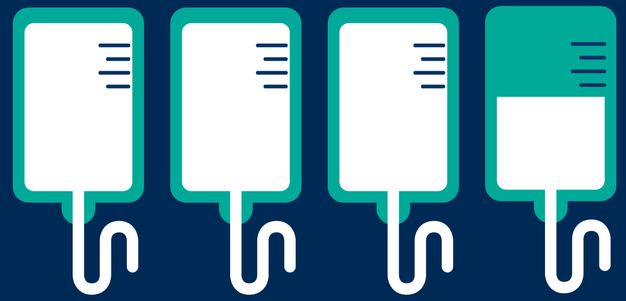

In the real-world study, 36 (28.8%) patients went on to receive maintenance IMFINZI following completion of the treatment regimen, with a median of 3.5 maintenance cycles reported.‡[1]

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Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting https://contactazmedical.astrazeneca.com/ or by calling 0800 783 0033.

IMFINZI in combination with gemcitabine and cisplatin is indicated for the 1L treatment of adults with locally advanced, unresectable, or metastatic BTC.[3]

Abbreviations:

1L, first line; AE, adverse event; BTC, biliary tract cancer; D, day; ECOG PS, Eastern Cooperative Oncology Group performance status; Gem-Cis, gemcitabine-cisplatin; MHRA, Medicines and Healthcare products Regulatory Agency; ORR, objective response rate; (m)OS, (median) overall survival; (m)PFS, (median) progression-free survival; PI, Prescribing Information; Q3/4W, every three/four weeks; RWE, real-world evidence; SmPC, summary of product characteristics; UK, United Kingdom.

References:

1. Daniels H, et al. *Cancers (Basel)*. 2025;17(17):2732; 2. Oh DY, et al. *NEJM Evid*. 2022;1(8):EVIDoa2200015; 3. IMFINZI. Summary of Product Characteristics.

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