# The Real-World Diagnostic Pathway In Patients With IgAN

R. Lafayette<sup>1</sup>; M. Kroes<sup>2</sup>; C. Aldworth<sup>2</sup>; L. Prieto<sup>2</sup>; AT. George<sup>3</sup>; W. Wang<sup>4</sup>; J. de Courcy<sup>5</sup> ; K. Golden<sup>5</sup>; E. Chatterton<sup>5</sup>; L. Yao<sup>6</sup>; D. Roccatello<sup>7</sup>

Affiliations: <sup>1</sup>Stanford University Medical Center, United States; <sup>2</sup>Novartis Pharma AG, Basel, Switzerland, <sup>3</sup>Novartis Healthcare Private Limited, Hyderabad, India; <sup>4</sup>Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States; <sup>5</sup>Adelphi Real World, Bollington, United Kingdom; <sup>6</sup>The First Hospital of China Medical University, Shenyang, PR China; <sup>7</sup>University of Turin, Turin, Italy

\*For any correspondence, please email Richard Lafayette: czar@stanford.edu

### Introduction

- Immunoglobulin A nephropathy (IgAN) is a rare disease with an estimated global annual incidence of 25/million<sup>1</sup>.
- Despite being a rare disease, IgAN is the most common form of primary glomerulonephritis worldwide<sup>1</sup>.
- In patients with primary glomerular disease, IgAN constitutes the main cause of kidney failure<sup>2</sup>.
- IgAN is associated with a poor prognosis, 30% or more of patients with >1g/day of proteinuria progress to kidney failure within ten years<sup>2</sup>.
- Poor prognosis is partly due to delayed diagnosis<sup>3</sup>.
- This analysis aims to describe the diagnostic pathway of patients with IgAN.

# Study design

- Data were drawn from the IgAN Disease Specific Programme™ (DSP), a
  point-in-time survey of nephrologists, and their IgAN patients, conducted in
  the EU5 (France, Germany, Italy, Spain, and the United Kingdom (UK)), the
  United States (US), China and Japan between June and October 2021.
- Ethics exemption was obtained from the Pearl Institutional Review Board and H. Clínic de Barcelona.
- The DSP methodology has been published previously in detail4.
- Ethics exemption was obtained from the Pearl Institutional Review Board.
- Nephrologists completed a structured online patient record form for each successive consulting IgAN patient providing information on patient's demographics, clinical data, and reasons for delay of diagnosis.
- Analyses presented are summarised descriptively

# Demographics

Table 1. Patient demographics by geographical region

	EU5	US	China	Japan
Number of patients, n	618	305	587	282
Age; mean (SD)	45.0 (14.9)	44.7 (14.7)	39.8 (13.7)	47.1 (16.2)
Sex, male; n (%)	413 (66.8)	169 (55.4)	329 (56.0)	141 (50.0)
BMI; mean (SD)	25.5 (4.3)	26.1 (4.7)	23.0 (2.6)	22.8 (3.9)
Working full/part time; n (%)	422 (68.3)	226 (74.1)	393 (67.0)	182 (64.5)
Diagnosis confirmed via kidney biopsy; n (%)	484 (78.3)	265 (86.9)	489 (83.3)	277 (98.2)

BMI; Body Mass Index; EU5 – France, Germany, Italy, Spain, and the United Kingdom; SD – Standard deviation; US – United States

## Results

Table 2. Physician-reported time of patient's symptom onset to first consultation with any physician and time from the patient's first consultation with any physician to an IgAN diagnosis.

	EU5	US	China	Japan
Number of patients, n	456	233	547	187
Time from symptom onset to first consultation (weeks); median (IQR*)	4.4 (0.5-9.3)	4.4 (1.3-11.9)	4.4 (0.6-14.0)	6.7 (2.0-21.6)
Number of patients, n	491	263	547	236
Time from first consultation to IgAN diagnosis (weeks); median (IQR)	5.3 (2.4-13.0)	4.0 (0.9-8.7)	2.6 (0.9-6.4)	8.4 (3.7-18.0)

EU5 – France, Germany, Italy, Spain, and the United Kingdom; IgAN – Immunoglobulin A nephropathy; IQR – Interquartile range; US – United States

# Table 3. Physician-reported patient estimated glomerular filtration rate and proteinuria (g/day) level at IgAN diagnosis

	EU5	US	China	Japan
Number of patients, n	465	240	438	213
eGFR (mL/min/1.73m²) level at diagnosis; mean (SD)	63.9 (30.2)	58.1 (25.7)	83.9 (28.9)	66.8 (21.4)
Number of patients, n	465	233	459	212
Proteinuria level at diagnosis; mean (SD)	2.9 (3.5)	2.3 (1.8)	2.3 (1.9)	1.1 (0.9)

eGFR – Estimated glomerular filtration rate; EU5 – France, Germany, Italy, Spain, and the United Kingdom; SD – Standard deviation; US – United States

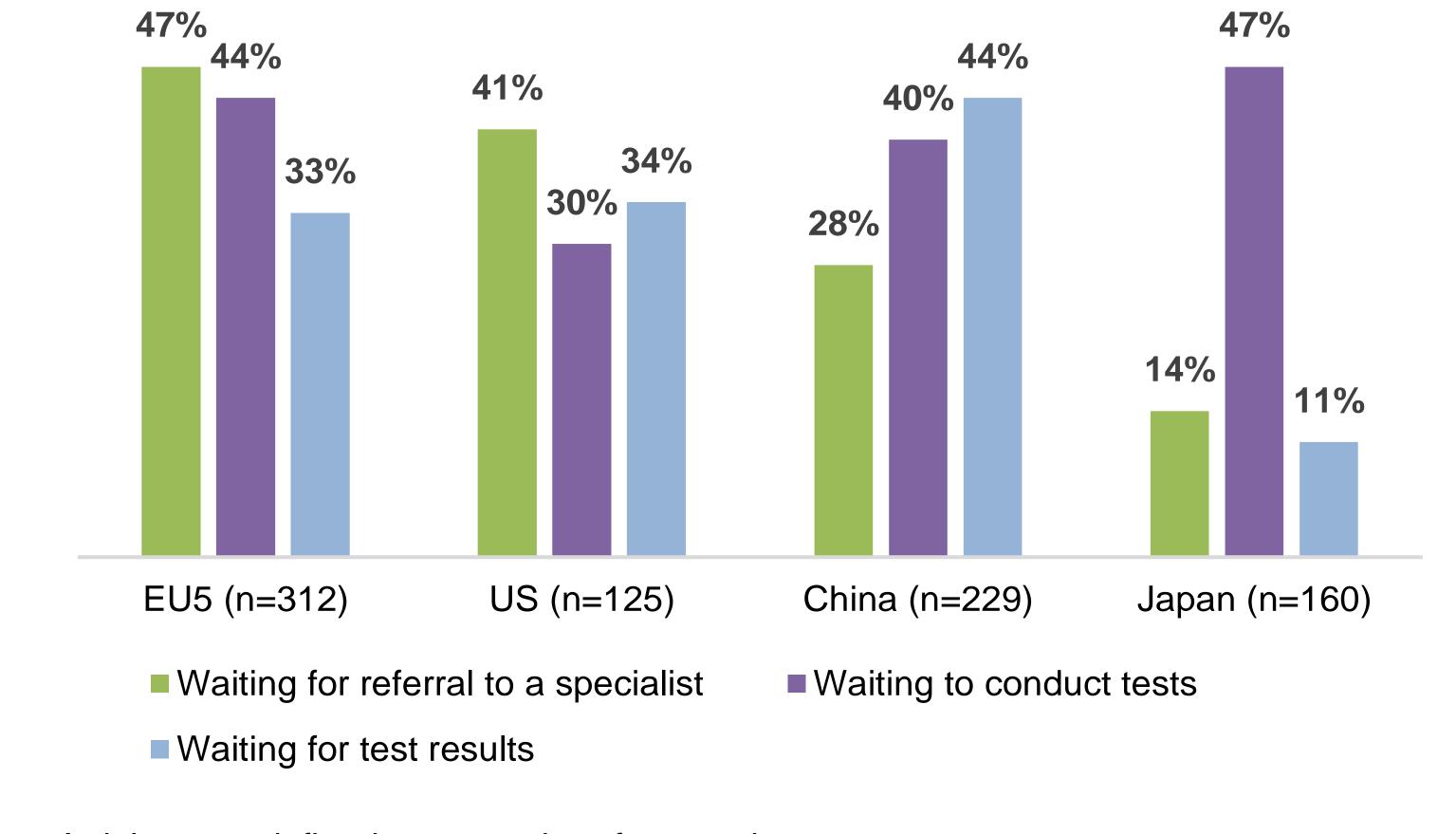
#### References

- 1. Storrar, J., Chinnadurai, R., Sinha, S., Kalra, P.A., 2022. The epidemiology and evolution of IgA nephropathy over two decades: A single centre experience. PLoS ONE, 17(9), e0268421.

  Reich, H., Troyanov, S., Scholey, J. and Cattran, D., 2007. Remission of Proteinuria Improves
- Reich, H., Troyanov, S., Scholey, J. and Cattran, D., 2007. Remission of Proteinuria Improves Prognosis in IgA Nephropathy. Journal of the American Society of Nephrology, 18(12), pp.3177-3183.
- Moresco, R. N., Speeckaert, M. M., & Delanghe, J. R. (2015). Diagnosis and monitoring of IgA nephropathy: the role of biomarkers as an alternative to renal biopsy. *Autoimmunity reviews*, 14(10), 847–853.
  - Anderson P, Benford M, Harris N, Karavali M, Piercy J. Real-world physician and patient behaviour across countries: Disease-Specific Programmes a means to understand. Current Medical Research and Opinion. 2008; 24(11):3063-3072.

### Results

Figure 1. Nephrologist reported top 3 reasons for a time delay<sup>a.</sup> between the patient's initial consultation with a physician and IgAN diagnosis



<sup>a.</sup> A delay was defined as more than four weeks EU5 – France, Germany, Italy, Spain, and the United Kingdom; IgAN – Immunoglobulin A

nephropathy; US – United States

Figure 2. Proportion of patients at chronic kidney disease stages 3b-5 based on eGFR at diagnosis (<45mL/min/1.73m²)

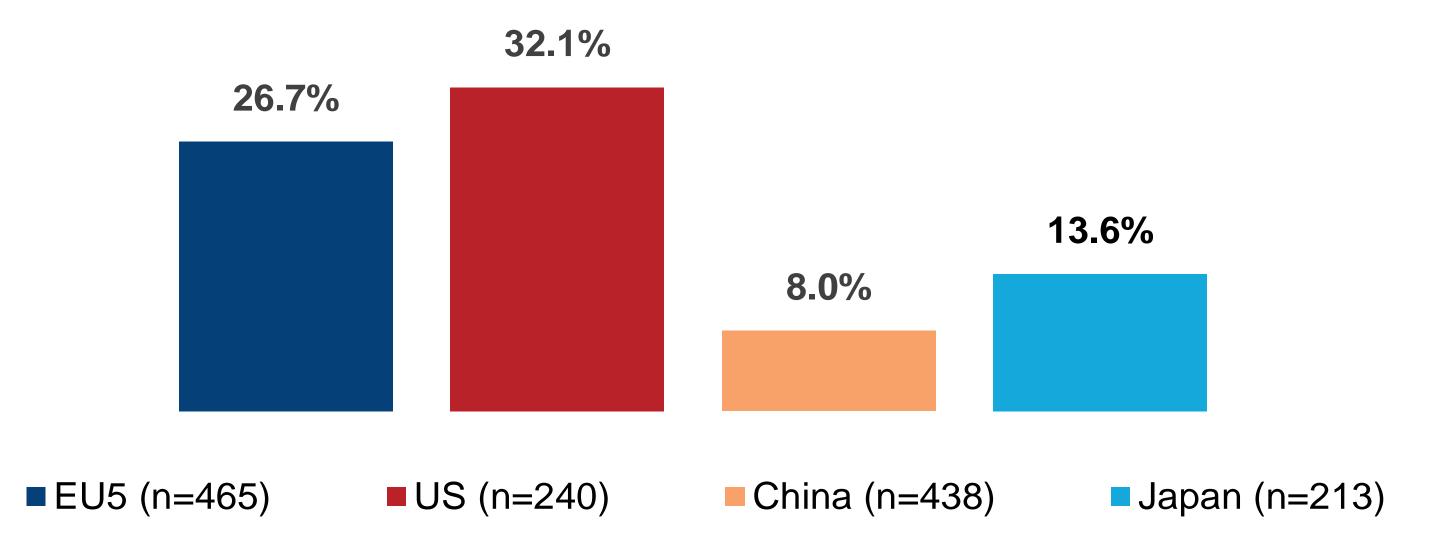
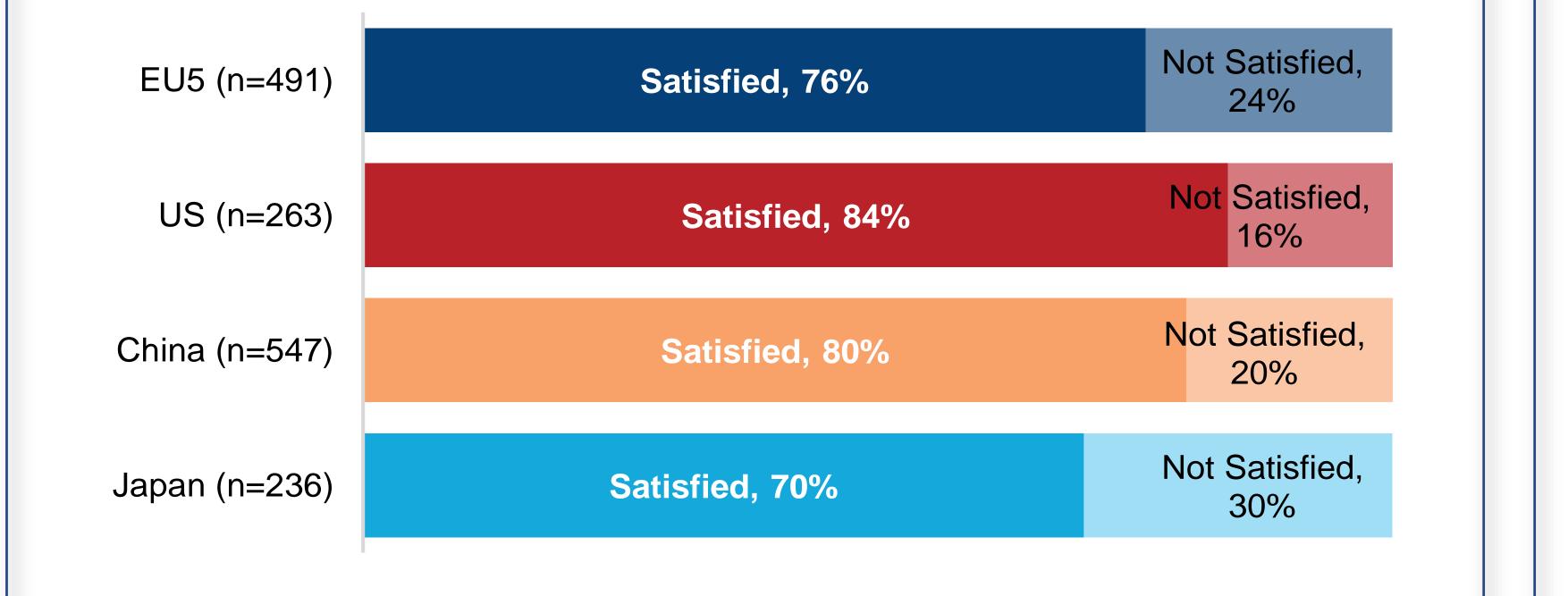


Figure 3. Percentage of patients for which physicians were satisfied vs. not satisfied with the diagnostic process (where physicians gave a response for satisfaction)



#### Results

Table 4. Physician-reported duration from first consultation to diagnosis (weeks) and whether they were satisfied vs not satisfied with the diagnostic process.

	EU5	US	China	Japan
		Satisfied		
Number of patients, n	374	220	439	166
Time from first consultation to IgAN diagnosis (weeks); median (IQR)	4.6 (2.1-10.6)	3.1 (0.7-6.9)	2.1 (0.6-4.6)	6.4 (3.7-14.9)
	N	lot satisfied		
Number of patients, n	117	43	108	70
Time from first				

EU5 – France, Germany, Italy, Spain, and the United Kingdom; IgAN – Immunoglobulin A nephropathy; IQR – Interquartile range; US – United States

(4.0-25.6)

consultation to

IgAN diagnosis

### Results

- A total of 295 nephrologists completed online patient record forms for 1792 patients. Mean patient age was 45.0 (14.9) years in the EU5, 44.7 (14.7) in the US, 39.8 (13.7) in China, and 47.1 (16.2 in Japan (**Table**
- Median time from symptom onset to the patient consulting any physician was reported for 79% of patients (n=1423). In the EU5 (n=456), US (n=233) and China (n=547), this was 4.4 weeks (Interquartile range (IQR) EU5: 0.5-9.3, IQR US: 1.3-11.9, IQR China: 0.6-14.0) and in Japan (n=187) this was 6.7 weeks (IQR: 2.0-21.6) (**Table 2**).
- Median time from first physician consultation to confirmed IgAN diagnosis was reported for 86% of patients (n=1537). In the EU5 (n=491) this was 5.3 weeks (IQR: 2.4-13.0), in the US (n=263) 4.0 weeks (IQR:0.9-8.7), in China (n=547) 2.6 weeks (IQR: 0.9-6.4), and in Japan (n=236) 8.4 weeks (IQR: 3.7-18.0) (**Table 2**).
- Patient estimated glomerular filtration rate (eGFR) (mL/min/1.73m²) levels were recorded by physicians at the time of diagnosis (63.9 EU5, 58.1 US, 83.9 China, 66.8 Japan) (Table 3).
- Patient proteinuria (g/day) levels were recorded by physicians at the time of diagnosis (2.9 EU5, 2.3 US, 2.3 China, 1.1 Japan) (**Table 3**).
- Reasons for a delay more than four weeks between first consultation and diagnosis were reported for 46% of patients (n=826). Waiting for a referral to a specialist (47% EU5, 41% US, 28% China, 14% Japan), waiting to conduct tests (44% EU5, 30% US, 40% China, 47% Japan), and waiting for test results (33% EU5, 34% US, 44% China, 11% Japan) were the most common (**Figure 1**).

#### Results

- Where eGFR was recorded at diagnosis (76%, n=1356) (**Figure 2**), patients at CKD stages 3b-5 (eGFR <45 mL/min/1.73m²) were 26.7% in the EU5, 32.1% in the US, 8.0% in China, and 13.6% in Japan.
- Physicians were not satisfied with the diagnostic process for 24% of the patients in the EU5, 16% in the US, 20% in China and 30% in Japan (Figure 3).
- Where physicians were not satisfied with the diagnostic process, the median duration from consultation to diagnosis for patients was notably longer than that of patients where physicians were satisfied with the diagnostic process (**Table 4**).

## Limitations

- The sample collected is not a probabilistic sample of patients as the methodology states that the next "n" consulting patients will be included.
- Patients included in the DSP sample are the next eligible patients who consult the physician; therefore, it may not truly represent the overall population of patients, as it is more likely to collect data on patients who consult more frequently.

### Conclusion

- The time from first physician consultation to IgAN diagnosis and eGFR mean at diagnosis varied depending on the geographical region the survey was completed in. Patients in China experienced the shortest time from first physician consultation to IgAN diagnosis and the lowest proportion of patients at CKD stages 3b-5 at diagnosis.
- Some patients are experiencing long durations between initial consultations and diagnosis. Reducing the duration from consultation to diagnosis may help to improve the level of physician satisfaction with the diagnostic pathway of patients.
- Improving the diagnostic process may improve prognosis for patients.

#### **Disclosures**

10.1

(4.3-44.5)

Data collection was undertaken by Adelphi Real World as part of an independent survey. Novartis is one of multiple subscribers to the DSP.

R. Lafayette is an employee of Stanford University Medical Center, his employers have received research funding from Omeros, Vera, Chinook, Alexion, Otsuka, Calliditas. R. Lafayette has provided consultancy for: Omeros. Vera, Calliditas, Chinook, Alexion, Otsuka, Novartis.

M. Kroes is an employee and shareholder of Novartis

C. Aldworth, L. Prieto, AT. George & W. Wang are employees of Novartis.

J. de Courcy, K. Golden & E. Chatterton are employees of Adelphi Real World.

L. Yao is an employee of First Hospital of China Medical University, and has received financial support for research programs from Novartis.

D. Roccatello is an employee of University of Turin, and has received financial support for research programs from Novartis, Alexion, GSK, Sandoz, Pfizer, and Roche.

The authors had full editorial control of the poster and provided their final approval of a content

#### Acknowledgments

Editorial assistance under the guidance of the authors was provided by Jade Garratt-Wheeldon of Adelphi Real World in accordance with Good Publication Practice (GPP3) guidelines

download a copy of this Poster

Presented at the American Society of Nephrology Kidney Week 2022, Orlando, FL, November 3–6, 2022

