

## touchPANEL DISCUSSION

CAR-T in clinical practice:  
Navigating the patient journey from  
referral to long-term follow-up

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An expert panel discussion  
recorded in July 2020

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## Expert panel



**Prof. Mohamad Mohty (Chair)**  
Professor of Hematology and  
Head of the Hematology and  
Cellular Therapy Department,  
Sorbonne University and  
Saint-Antoine Hospital,  
Paris, France



**Dr John Kuruvilla**  
Associate Professor of Medicine  
and Hematologist,  
University of Toronto and  
Princess Margaret Cancer Centre,  
Toronto, Canada



**Dr Robin Sanderson**  
Consultant Haematologist  
and lead of the lymphoma  
CAR-T programme,  
King's College Hospital,  
London, UK

# Agenda

## **What is the real-world evidence for CAR-T therapy in patients with DLBCL and what does it mean for clinical practice?**

*Presentation:* Mohamad Mohty

*Panel discussion:* John Kuruvilla and Robin Sanderson; moderated by Mohamad Mohty

## **Why is early referral for CAR-T therapy important and how do we select patients for referral?**

*Presentation:* Mohamad Mohty

*Panel discussion:* John Kuruvilla and Robin Sanderson; moderated by Mohamad Mohty

## **How can referral centres and treatment centres collaborate for optimal patient care?**

*Presentation:* Mohamad Mohty

*Panel discussion:* John Kuruvilla and Robin Sanderson; moderated by Mohamad Mohty

A hand in a white lab coat sleeve holds a silver pen over a wireframe globe. The background is a blurred clinical setting. The text is overlaid in orange.

## What is the real-world evidence for CAR-T therapy in patients with DLBCL and what does it mean for clinical practice?

CAR-T, chimeric antigen receptor T-cell; DLBCL, diffuse large B-cell lymphoma.

# Using real-world data to improve decision making<sup>1,2</sup>

## Randomized controlled trial



- Pre-defined patient inclusion and exclusion criteria

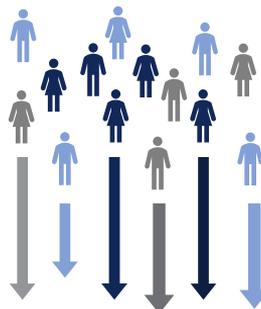


- Coordinated and standardized data collection and analysis



Test safety and efficacy of a treatment in a controlled system before routine clinical practice

## Real-world data



- Generated during routine clinical practice
- Data collected from a broad range of sources



### Value of real-world data:

- Complement data from randomized controlled trials
- Generate insights about how a medicine is used



### Limitations of real-world data:

- Variable sources and types of data may limit the generalizability of the results
- Reproducibility requires standardized datasets, protocols and tools

# Real-world data from the UK – EHA25 Virtual

## High-grade lymphoma patients treated with CD19 CAR-T<sup>1</sup>



England,  
NCCP



N=183  
patients



Dec 2018 –  
Jan 2020

### Adverse effects (Axi-cel + Tisagen)

	% (n/N)
Grade ≥3 CRS	8% (15/183)
Grade ≥3 ICANS	15% (27/183)

### Treatment response (Axi-cel + Tisagen)

	% (n/N)
ORR 3 months	42% (65/156)
ORR 6 months	32% (36/114)

## High-grade neurological toxicity following CD19 CAR-T<sup>2</sup>



London,  
UCLH



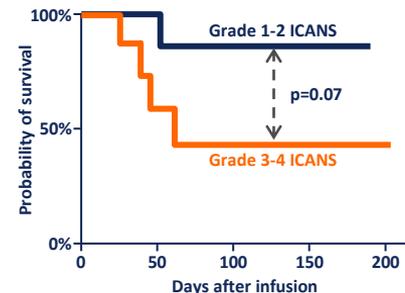
N=44  
patients



Apr 2019 –  
Mar 2020

### Adverse effects (Axi-cel + Tisagen)

	% (n/N)
Grade ≥3 ICANS	18% (8/44)



! Patients with high-grade ICANS had a trend towards lower survival

Axi-cel, axicabtagene ciloleucel; CAR-T, chimeric antigen receptor T-cells; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; NCCP, National CAR-T Clinical Panel; ORR, overall response rate; Tisagen, tisagenlecleucel; UCLH, University College London Hospital.

1. Kuhn A, et al. EHA25 Virtual 2020 [Oral presentation p428–4; Abstract S243]. 2. Mackenzie S, et al. EHA25 Virtual 2020 [Poster EP1510].

# Real-world data from France – EHA25 Virtual

## CD19 CAR-T in patients with relapsed/refractory large B-cell lymphoma<sup>1</sup>



France,  
Lyon Sud Hospital



N=61  
patients



Jan 2017 –  
Nov 2019

### Adverse effects (Axi-cel + Tisagen)

	% (n/N)
Grade $\geq 3$ CRS	8% (5/61)
Grade $\geq 3$ ICANS	10% (6/61)

- ! • CRS and neurotoxicity occurred less frequently than in clinical trials<sup>2,3</sup>

### Treatment response (Axi-cel + Tisagen)

	% (n/N)
ORR 1 month	63% (37/59)
ORR 3 months	45% (25/56)

- ! • ORR 1 month after infusion confirms early efficacy of CAR-T
- Rapid relapses seem to occur at a higher frequency than previously reported<sup>2,3</sup>

Axi-cel, axicabtagene ciloleucel; CAR-T, chimeric antigen receptor T-cells; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; ORR, overall response rate; Tisagen, tisagenlecleucel.

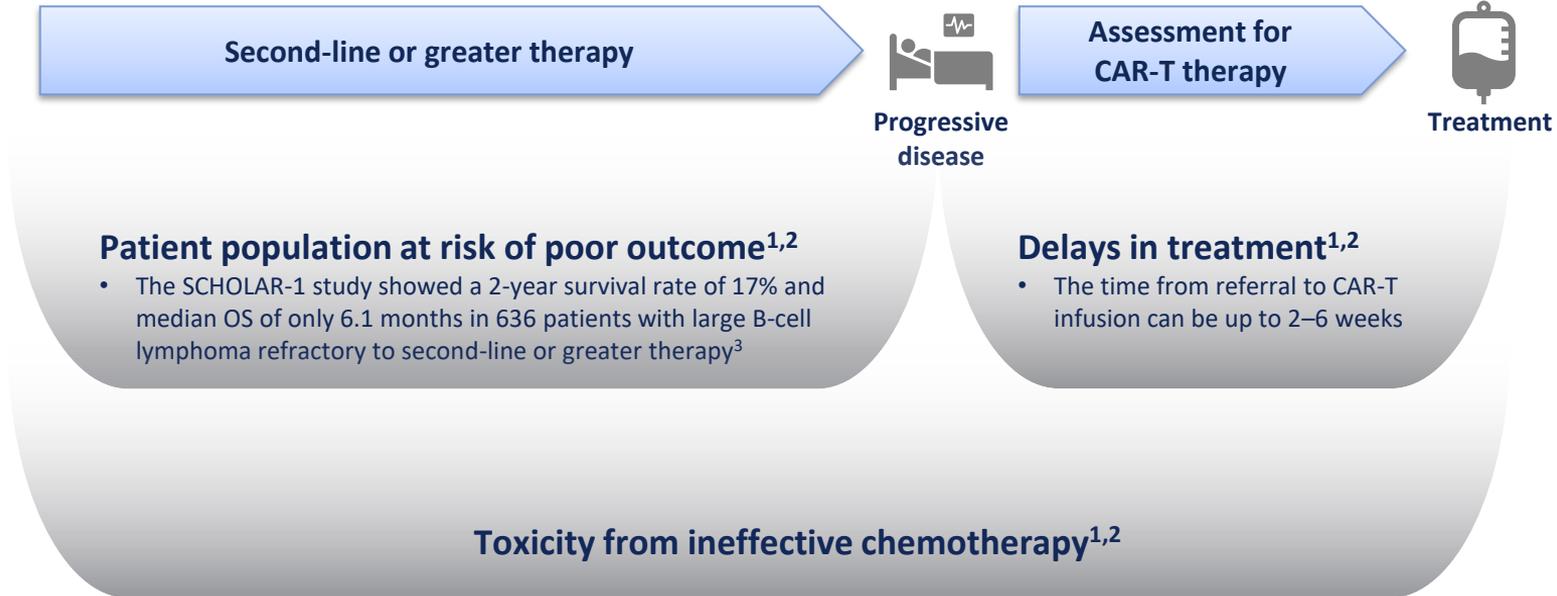
1. Sesques P, et al. EHA25 Virtual 2020 [poster EP1211]; 2. Locke FL, et al. *Lancet Oncol.* 2019;20:31–42. 3. Schuster SJ, et al. *N Engl J Med.* 2019;380:45–56.

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## Why is early referral for CAR-T therapy important and how do we select patients for referral?

CAR-T, chimeric antigen receptor T-cell.

# Importance of early referral for CAR-T therapy



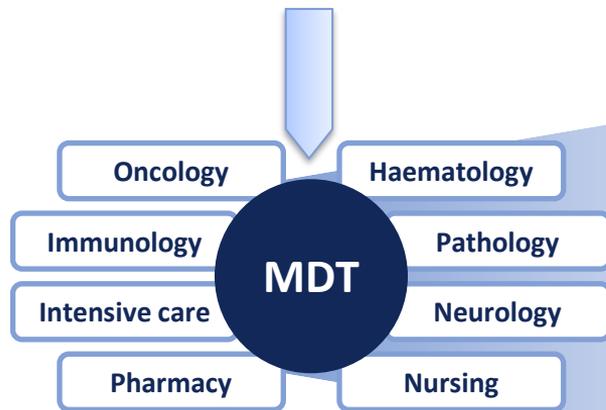
CAR-T, chimeric antigen receptor T-cell; HSCT, Hematopoietic stem cell transplant; ORR, overall response rate.

1. Chavez JC, et al. *Ther Adv Hematol.* 2019;10:1–20. 2. Jacobson CA, et al. *Oncologist.* 2020;25:e138–46. 3. Crump M, et al. *Blood* 2017;130:1800–8.

# Role of a multidisciplinary team in the decision to treat and management of patients



The decision to treat a patient with CAR-T therapy is made by a MDT at a designated treatment centre<sup>1-3</sup>



- Review of diagnosis and indication for treatment
- Evaluation of risks
- Clinical decision making
- Expert advice for complex cases
- Advice and review of informed consent
- Management of treatment, post-treatment and follow-up

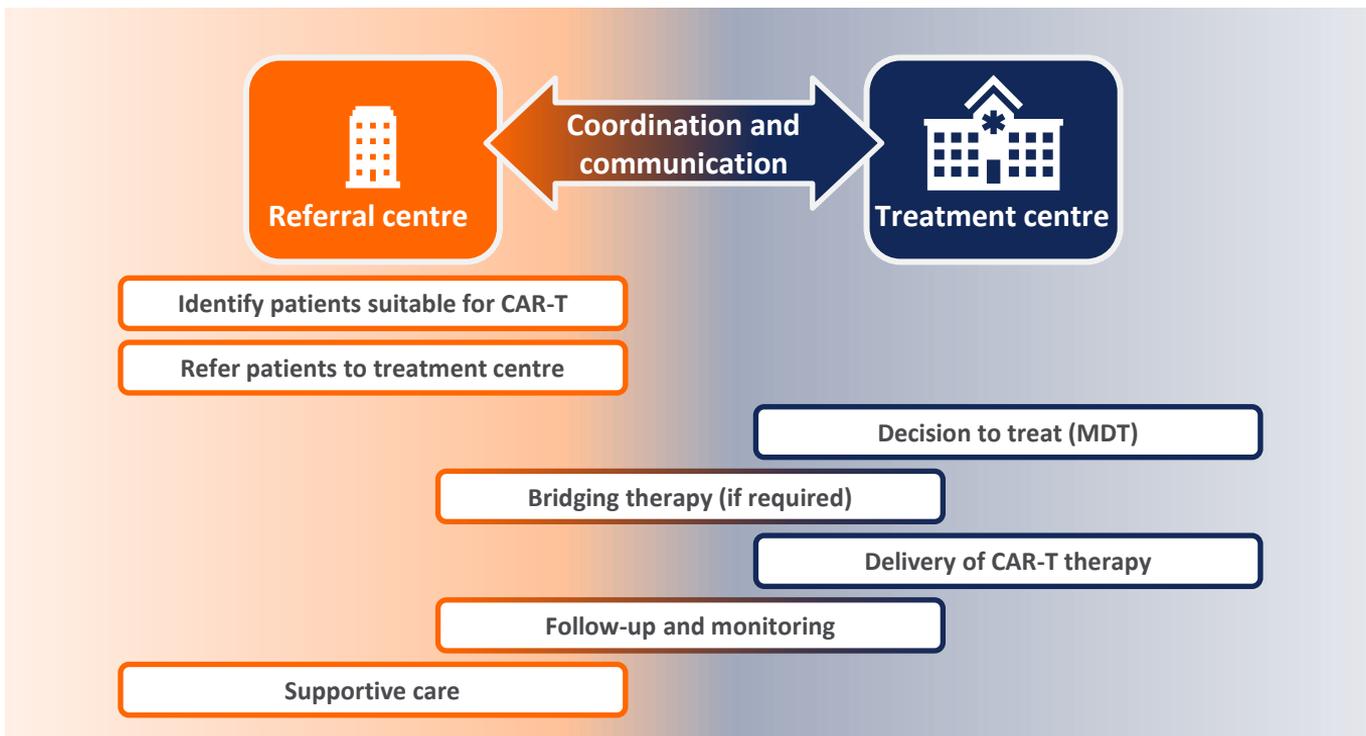
CAR-T, chimeric antigen receptor T-cell; MDT, multidisciplinary team.

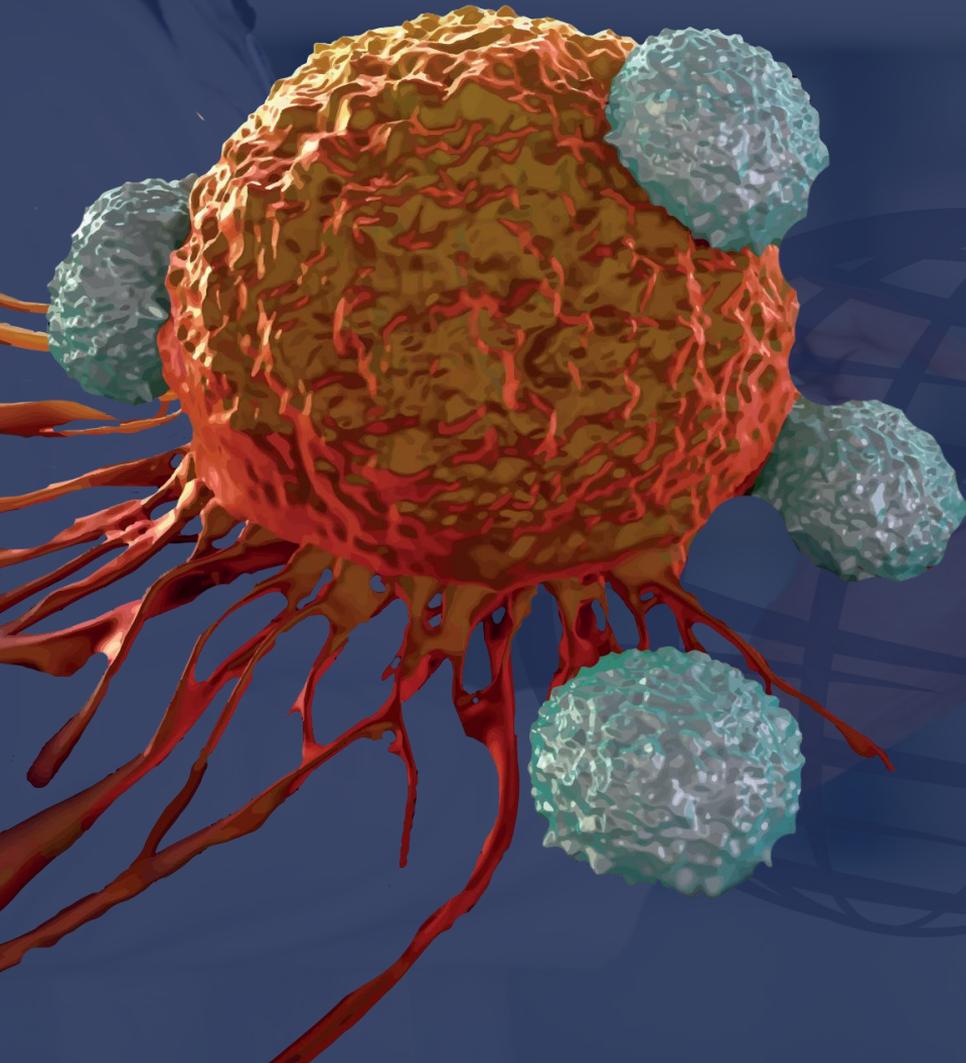
1. Chomiene C, et al. *HemaSphere*. 2019;03:04. 2. NHS England. CAR-T therapy. Service specification nos. 170100S and 170099S. Available at: [www.england.nhs.uk/wp-content/uploads/2018/12/Tisagenlecleucel-Chimeric-Antigen-Receptor-T-Cell-CAR-T-Therapy-for-ALL-and-DLBCL.pdf](http://www.england.nhs.uk/wp-content/uploads/2018/12/Tisagenlecleucel-Chimeric-Antigen-Receptor-T-Cell-CAR-T-Therapy-for-ALL-and-DLBCL.pdf) and [www.england.nhs.uk/wp-content/uploads/2018/12/Axicabtagene-Ciloleucel-Chimeric-Antigen-Receptor-T-Cell-CAR-T-Therapy-for-the-treatment-of-adult-patients-wit.pdf](http://www.england.nhs.uk/wp-content/uploads/2018/12/Axicabtagene-Ciloleucel-Chimeric-Antigen-Receptor-T-Cell-CAR-T-Therapy-for-the-treatment-of-adult-patients-wit.pdf), respectively (accessed 3 July 2020). 3. Yakoub-Agha I, et al. *Haematologica*. 2020;105:297-316.



**How can referral centres and treatment centres collaborate for optimal patient care?**

# The roles of referral and treatment centres at different stages of the patient pathway<sup>1</sup>





**Thank you for watching  
this on-demand event**

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