

### Background

CAR T-cell therapies are a very promising treatment option for many patients with hematological malignancies. However, the evidence on the long-term safety and effectiveness of these treatments is limited. The European Medicines Agency (EMA) obliges marketing authorization holders (MAHs) to conduct post-authorization studies (PAS) to monitor the long-term safety and effectiveness of CAR T-cell therapies.

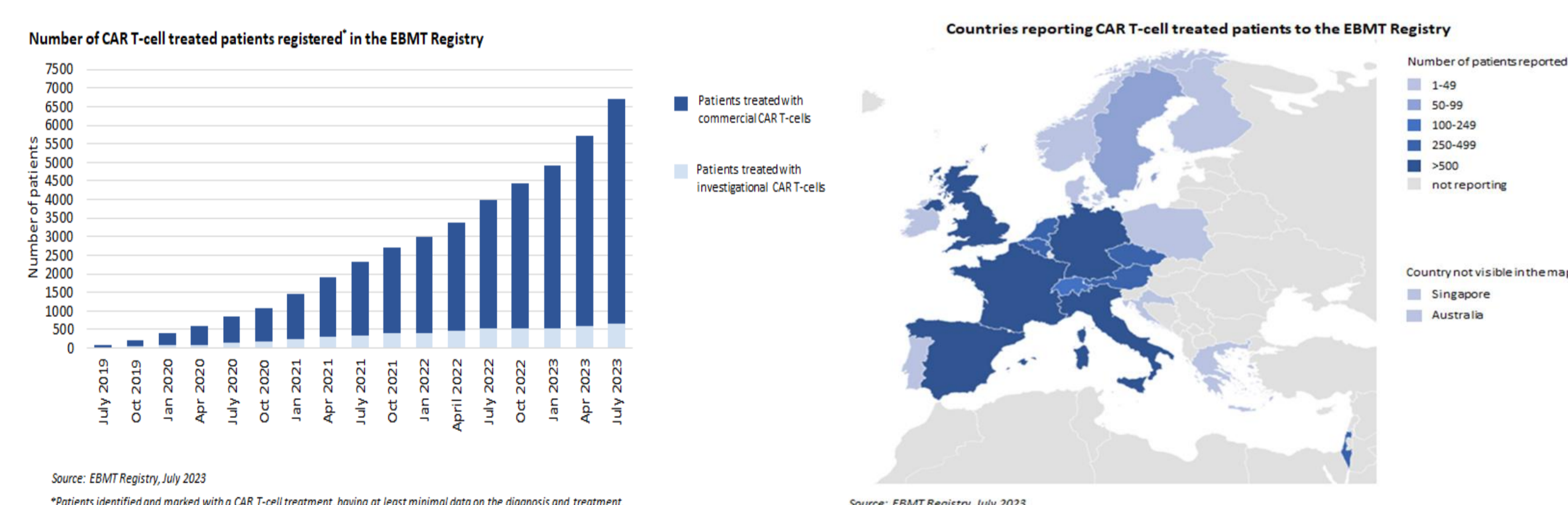
EMA has recommended MAHs to conduct their PAS with a 15-year follow-up using the data captured in the EBMT Registry. This data includes safety and effectiveness data on infectious and non-infectious complications which are of special interest, as captured on the EBMT Cellular Therapy Form.

EBMT's collaboration with the MAH's lessens the burden of work through uniform processes of data collection for participating sites and ensures that the collected data is not siloed in private databases of MAHs but remains available to academic research through the EBMT Registry.

**EBMT encourages the centers participating in the Data Collection Initiative (DCI) to complete the data for the patients they have reported to support the PAS studies mandated by EMA**

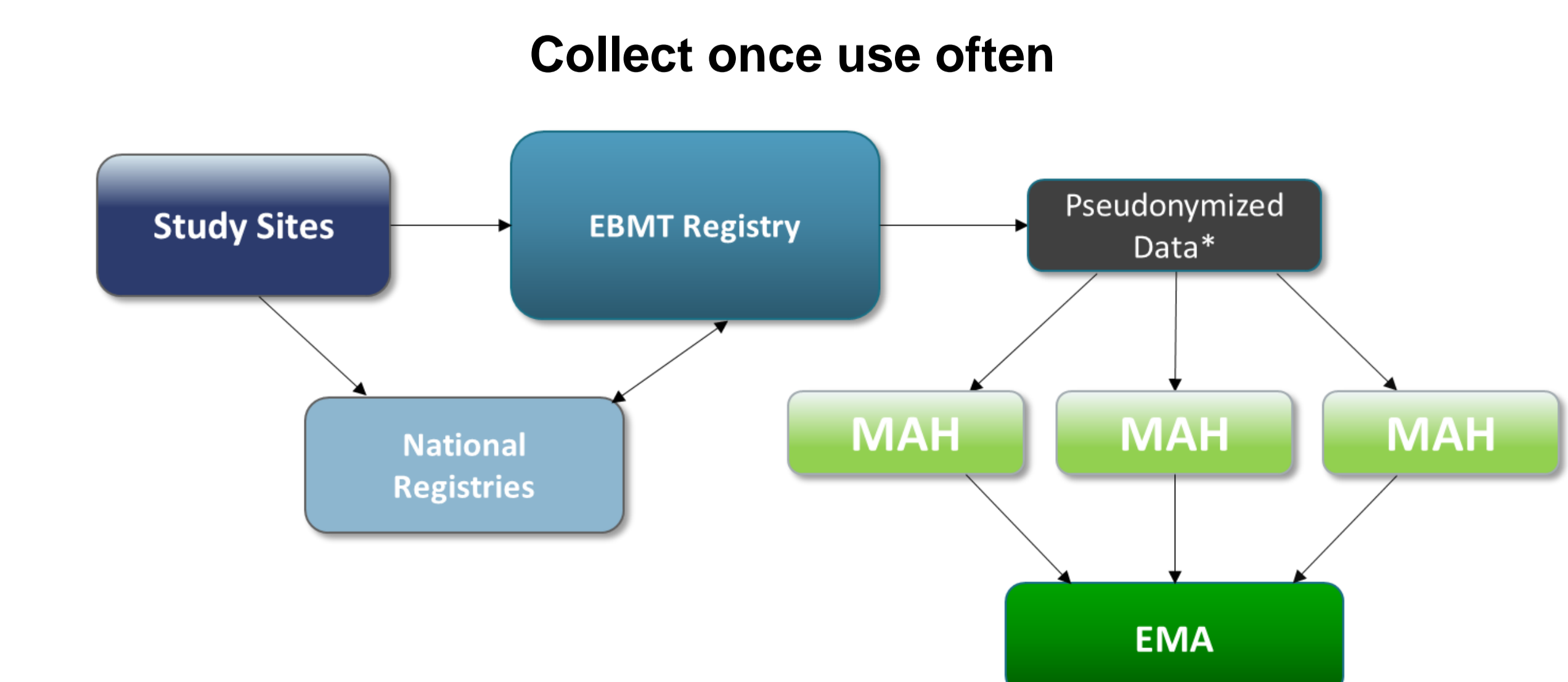
### CAR T-cell data in the EBMT Registry

Currently >700,000 patients that received HCT and >7,900 patients with CAR T-cell therapies are registered in the EBMT Registry



**Please register all your consecutive CAR-T patients in the EBMT Registry**

### CAR-T Data Collection Initiative (DCI)



\*Patients need to consent to sharing pseudonymized data with MAH

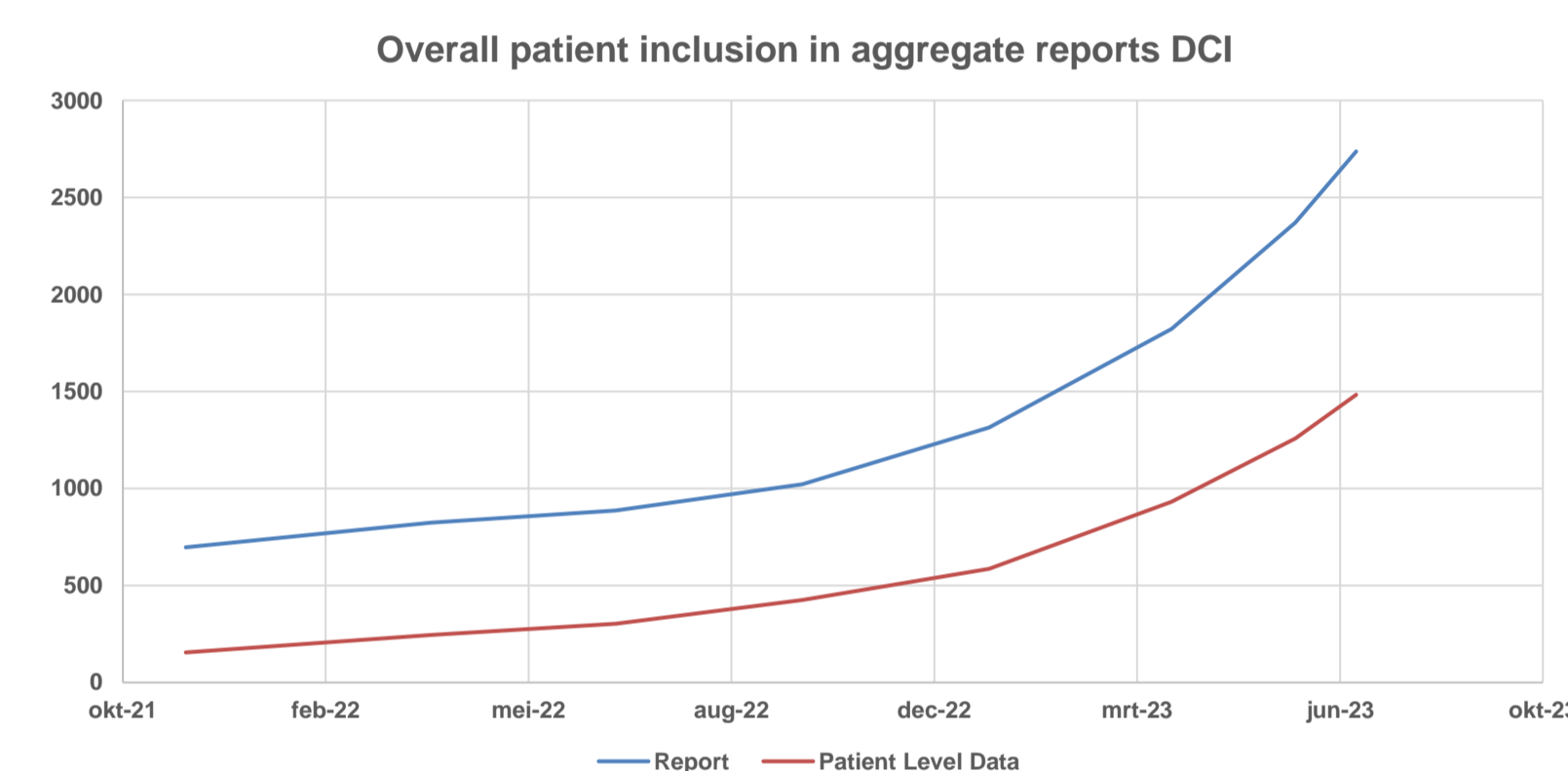
### Inclusion criteria

- Patients treated with commercial CAR-T products
- Patients who have consented to share data with the EBMT Registry and their pseudonymized data with the MAH

### DCI status

Status of the PAS within the DCI till the 19th of July 2023

Manufacturer	Product	Enrolment period	Contracted indications	Enrolment (target)	No patients included (% accrual)
Kite	Yescarta	2020-2023	DLBCL+PMBCL	Closed	1471 (100%)
Novartis	Kymriah	2020-2023	ALL+DLBCL	Closed	800 (100%)
Celgene-BMS	Abecma	2021-	MM	300	154 (51%)
Celgene-BMS	Breyanzi	2022-	DLBCL+PMBCL+FL	200	6 (3%)
Kite	Tecartus	2023-	MCL	300	145 (48%)



### CAR T-cell Data Entry

#### Data entry in the EBMT Registry

- The Data Collection Forms (DCF) and Completion Guidelines can be found on the EBMT website: <https://www.ebmt.org/registry/ebmt-data-collection>
- Link to the new EBMT Registry: <https://registry.ebmt.org/>

#### Data collection timepoints

- **Day 0** - Two forms need to be completed:
  - Disease Status at Treatment
  - Cellular Therapy Day 0
- **Day 100, 6 months and annually:**
  - Cellular Therapy FU forms should be completed
- **Note:** Please make sure you also register the diagnosis using the diagnosis-specific form and complete the information on pre- and post-HCT treatments, if available
- Please try to enter the data within 6 weeks after patient visit/consent of the patient

### High quality CAR-T data & benefits for centers

- Sites can use their own CAR-T Registry data for publications
- High quality of data collected because 10% of the patients will be Source Data Verified (SDV)
- Financial compensation for the sites which have signed a contract with EBMT

### Contact

If you have questions, please contact your **country lead** or send your question to the Registry Helpdesk at: [registryhelpdesk@ebmt.org](mailto:registryhelpdesk@ebmt.org)

For more information, check our website: <https://www.ebmt.org/registry/ebmt-car-t-data-collection-initiative>