

Cell Orchestration Platform (COP)

Autolus

Funded by



UK Research
and Innovation

Coordinated by

CATAPULT
Cell and Gene Therapy

Executive Summary

There is a distinct need for all manufacturers of cell and gene therapy ATMP products, particularly in the autologous setting, to implement a scalable solution for maintaining chain of identity and tracking patient cell/product throughout its journey. The ecosystem of commercial cell tracking software remains relatively nascent, with no clear industry standard solution.

The Vision for this Project was to map the current landscape for electronic cell orchestration software platform providers and develop a roadmap for establishment of a scalable personalized therapy platform.

- Define business needs in terms of pathway from clinical development to commercial and estimated scale at each stage
- Map current technology providers and platforms across the cellular therapy/BMT/stem cell transplant software space
- Map customer base for each offering
- Perform a gap analysis to establish capabilities across the space

By the end of the Project, Autolus had obtained feedback from clinical sites and had evaluated commercial cell tracking system providers and selected one of these. Autolus plans to have ready a validated electronic COP in time for the launch of their first product.

User survey

The digital platform questionnaire received engagements from 14 participants. 7 of these participants did not complete the questionnaire, resulting in 7 successfully completed surveys which have been collated and summarised below. Further to this, Autolus were pleased to see that half of the survey participants have also agreed to a follow up discussion to continue this important exercise.

From the survey responses it was clear that most individuals interact with their preferred platform on a weekly, if not daily basis. When rating the user experience with their favoured platform, the overall experience was good, however individuals highlighted the following areas for improvement: information regarding drug manufacturing and drug product transportation, and the processes around drug administration and long term follow up. When relating this question to the least favourite platform, the processes for patient enrolment, patient scheduling & order placement, and information regarding drug manufacturing were rated the lowest.

When asked what is currently missing which would aid their internal processes, comments included access to specific dates that are available for apheresis, a live booking system with up-to-date information on the cells estimated completion date, and automatic updates from the portal on changes being made by local CAR-T team to help the pharmacy manage orders.

The survey highlighted that most available platforms do not integrate with other systems already in place nor do they integrate with data information into Electronic Medical Record (EMR) systems. One individual stated that patient ID numbers, access to certificate of release and key product pathway dates were important areas for future integration. Furthermore, these platforms currently do not have the capability to integrate data and information into the CAR-T registry.

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Individuals completing this survey highlighted that training was provided on the platforms they currently use; however they do not offer any patient facing digital platforms as part of their package. They identified a few key areas for future manufacturers to address including ease of use when adding and schedule patients, ability to track product and receive updates on cell processes status and harmonisation across platforms.

In conclusion it is clear from this survey that although there are strengths in the platforms currently in use, future systems need to focus on integration, ease of use and communication to keep the user fully updated on all aspects within the platform.

The detailed results from this survey are presented below.

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Digital Platform Experience Questionnaire

Questions including personal data have been removed

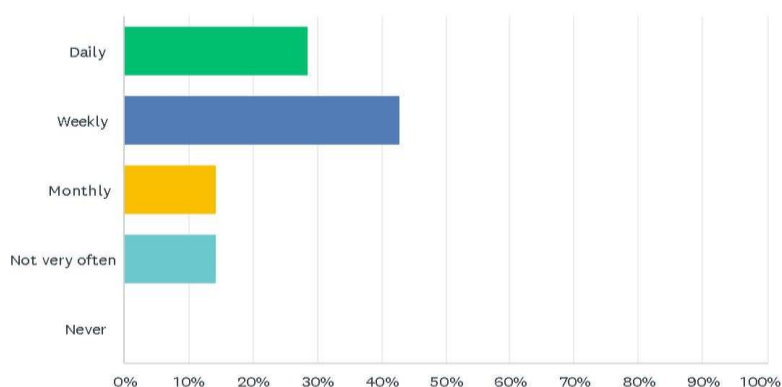
Q2 What clinical and/or commercially available CAR-T therapies are available at your centre?

#	RESPONSES	DATE
1	Yescarta, Tecartus, Kymriah plus various clinical trials	12/9/2021 4:31 PM
2	Yescarta, Tecartus, Tisagen	12/9/2021 12:42 PM
3	Kymriah, Yescarta, Tecartus plus trials	12/9/2021 11:11 AM
4	Kymriah, Yescarta, Tecartus	12/9/2021 10:40 AM
5	Axicel/Tecartus/Kymriah [plus multiple research products	12/9/2021 10:19 AM
6	NOVARTIS Tisagenlecleucel, KITE Tescarta, KITE Tecartus	12/6/2021 11:47 AM

Q3 Which CAR-T Therapy Manufacturer Portal(s) are you currently using? If multiple, please indicate which portal works best for your centre.

#	RESPONSES	DATE
1	CellChain and preferred -KiteConnect	2/14/2022 8:28 AM
2	Currently using Kite Connect and Novartis Cellchain - both work well but from a pharmacy point of view it would be useful if pharmacy were able to approve the order and add the order number on the Kite Connect like we are able to on Novartis Cellchain and for this reason I would say that Novartis Cellchain is preferable	12/9/2021 4:31 PM
3	Kite Connect	12/9/2021 12:42 PM
4	Novartis	12/9/2021 11:11 AM
5	Cell Chain Platform (preferred), Kite Connect	12/9/2021 10:40 AM
6	Multiple -cell chain	12/9/2021 10:19 AM
7	CellChain	12/6/2021 11:47 AM

Q4 In relation to the portal that works best, how often do you interact with the digital platform offered by the manufacturer?

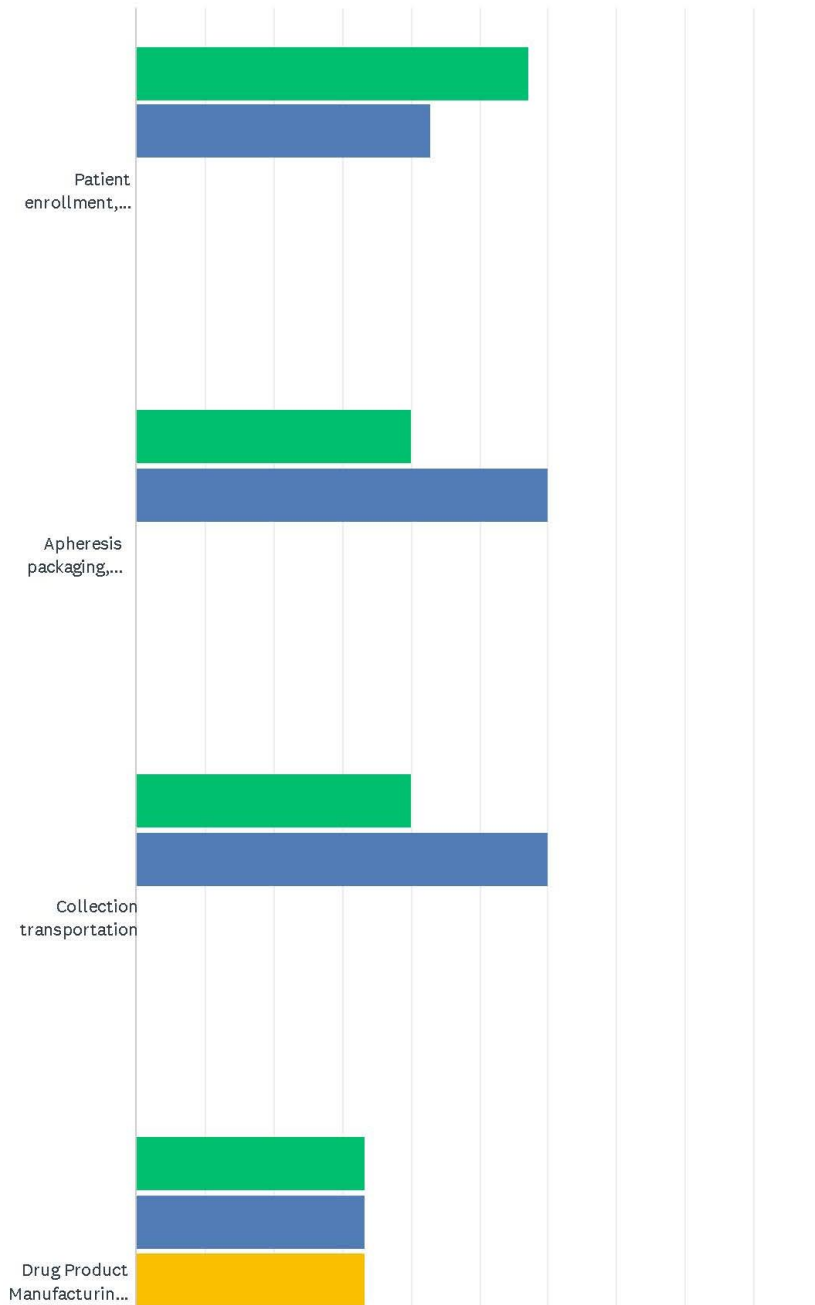


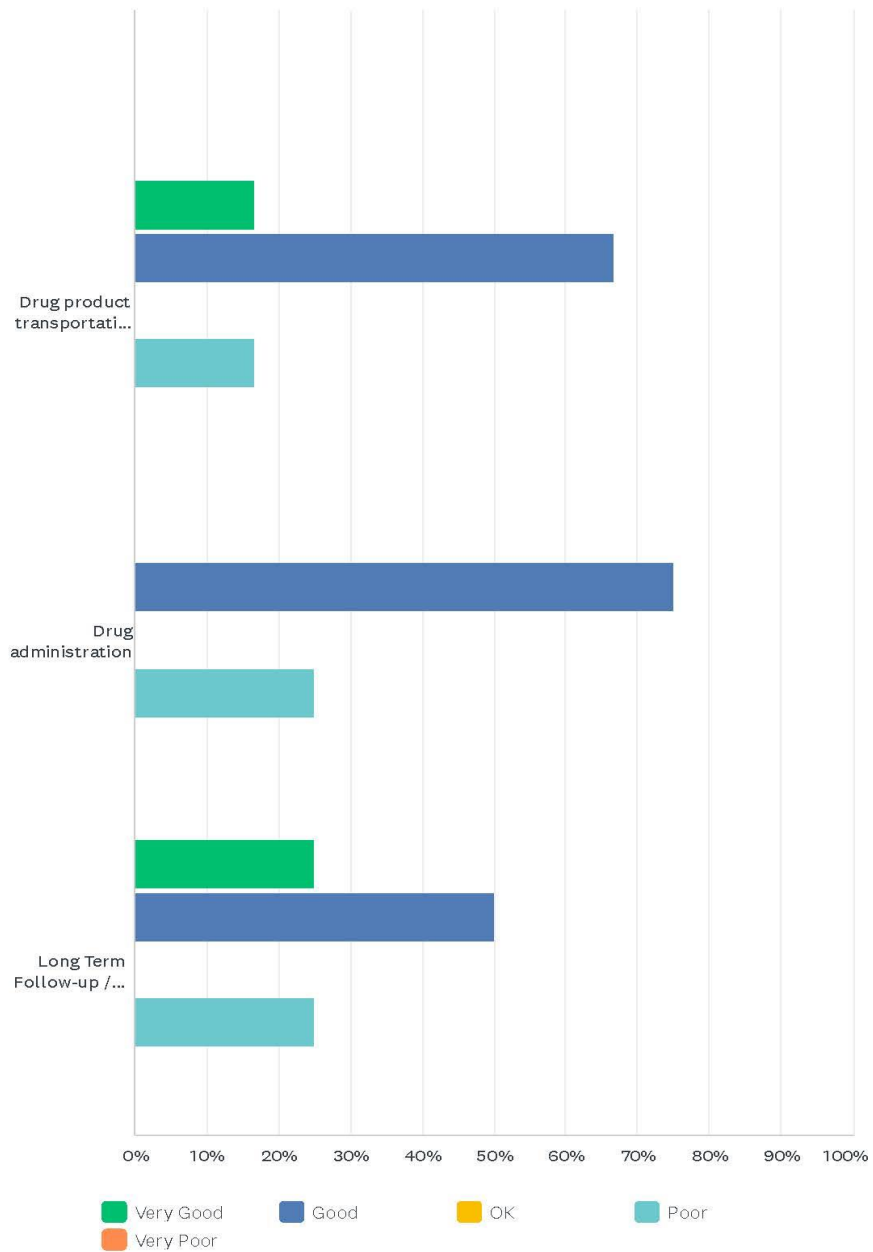
ANSWER CHOICES	RESPONSES	Count
Daily	28.57%	2
Weekly	42.86%	3
Monthly	14.29%	1
Not very often	14.29%	1
Never	0.00%	0
TOTAL		7

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Q5 Thinking about the portal that works best for you, please rate your user experience in relation to the key processes below:



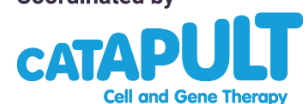


	VERY GOOD	GOOD	OK	POOR	VERY POOR	TOTAL
Patient enrollment, Patient scheduling & Order Placement	57.14% 4	42.86% 3	0.00% 0	0.00% 0	0.00% 0	7
Apheresis packaging, labeling & collection	40.00% 2	60.00% 3	0.00% 0	0.00% 0	0.00% 0	5
Collection transportation	40.00% 2	60.00% 3	0.00% 0	0.00% 0	0.00% 0	5
Drug Product Manufacturing (status updates, leading up to quality review)	33.33% 2	33.33% 2	33.33% 2	0.00% 0	0.00% 0	6
Drug product transportation & Product receipt	16.67% 1	66.67% 4	0.00% 0	16.67% 1	0.00% 0	6
Drug administration	0.00% 0	75.00% 3	0.00% 0	25.00% 1	0.00% 0	4
Long Term Follow-up / Registry	25.00% 1	50.00% 2	0.00% 0	25.00% 1	0.00% 0	4

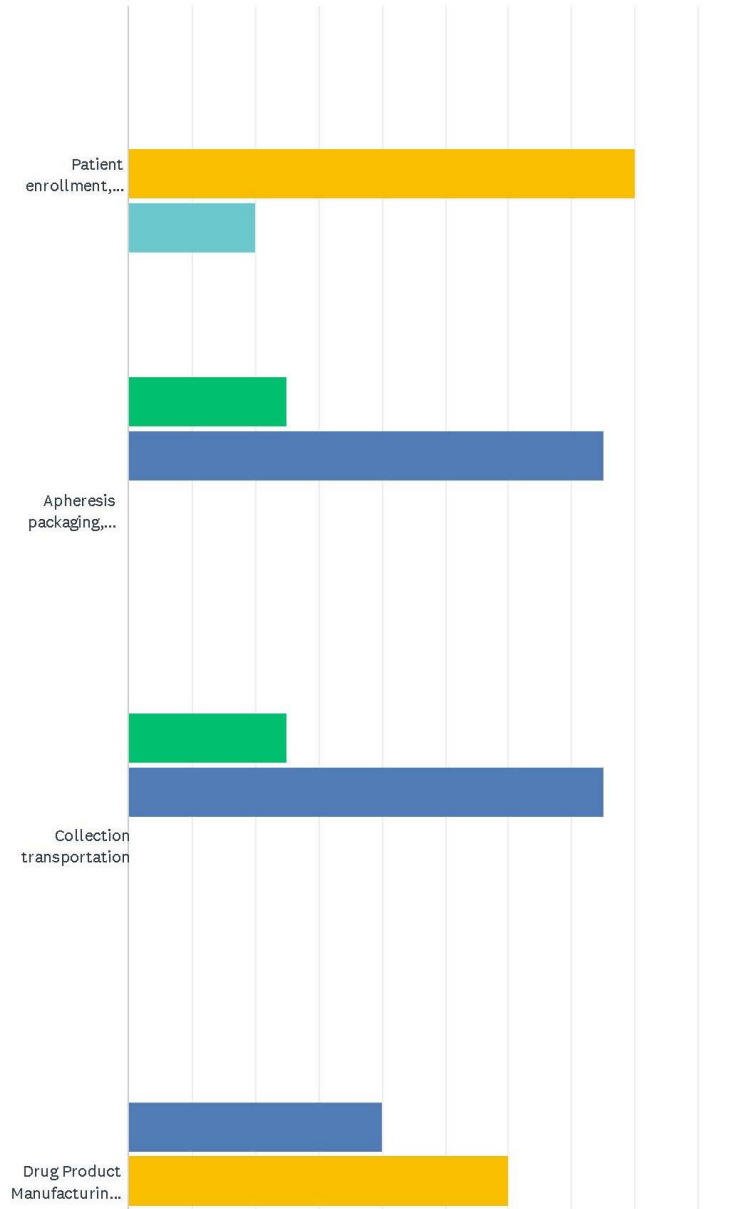
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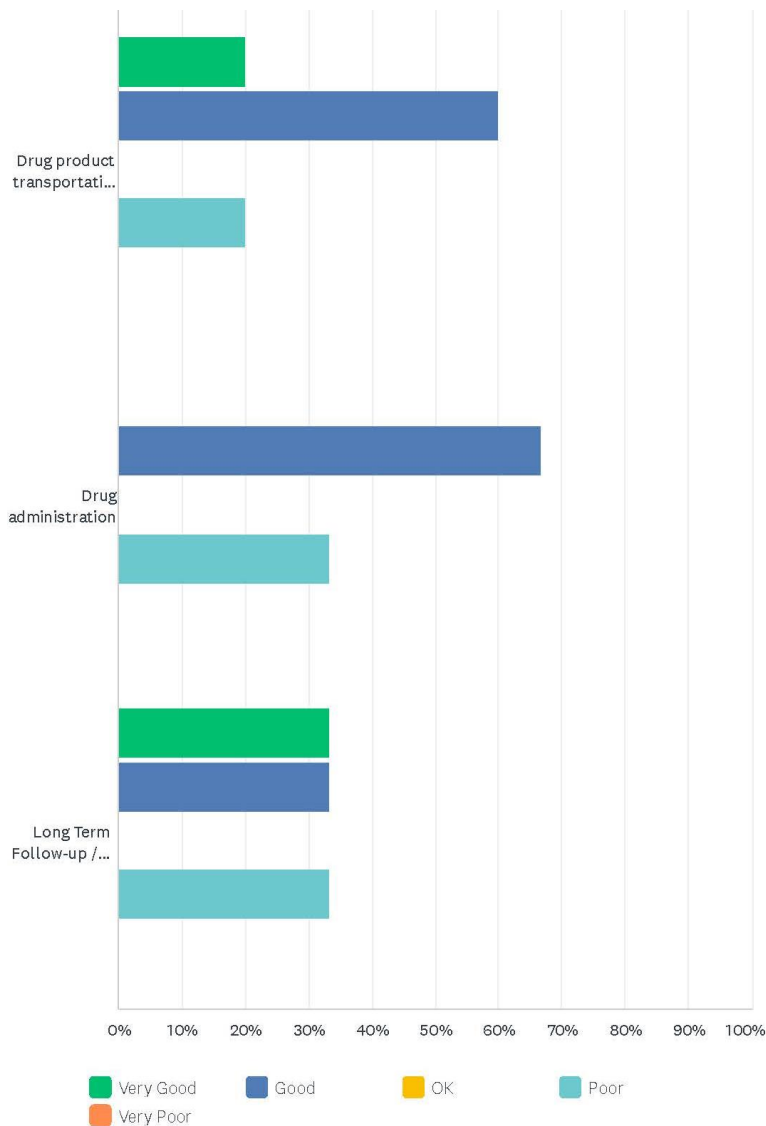


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Q6 If applicable, please now rate your experience using the digital platform you feel is the most difficult to work with at your centre.





	VERY GOOD	GOOD	OK	POOR	VERY POOR	TOTAL
Patient enrollment, Patient scheduling & Order Placement	0.00% 0	0.00% 0	80.00% 4	20.00% 1	0.00% 0	5
Apheresis packaging, labeling & collection	25.00% 1	75.00% 3	0.00% 0	0.00% 0	0.00% 0	4
Collection transportation	25.00% 1	75.00% 3	0.00% 0	0.00% 0	0.00% 0	4
Drug Product Manufacturing (status updates, leading up to quality review)	0.00% 0	40.00% 2	60.00% 3	0.00% 0	0.00% 0	5
Drug product transportation & Product receipt	20.00% 1	60.00% 3	0.00% 0	20.00% 1	0.00% 0	5
Drug administration	0.00% 0	66.67% 2	0.00% 0	33.33% 1	0.00% 0	3
Long Term Follow-up / Registry	33.33% 1	33.33% 1	0.00% 0	33.33% 1	0.00% 0	3

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Q7 Thinking about the platform that works least well, what were the main issues you encountered?

#	RESPONSES	DATE
1	-Difficulties figuring out what dates are available -Communication with the company	2/14/2022 8:28 AM
2	Kite Konnect from a Pharmacy point of view Unable to approve the order on the portal Unable to add the order number for the product on the portal	12/9/2021 4:31 PM
3	Not having up-to date information on when cells pass the quality check on the platform and not being able to book slots through the platform.	12/9/2021 12:42 PM
4	I only use one platform	12/9/2021 11:11 AM
5	Enrolment notifications are not automated, often rely on co-ordination team or company's cell therapy manager to inform when an approval/PO number required. Certificates of release are not always available and require chasing. Have to manually email cell manager to confirm stock of tocilizumab for each patient	12/9/2021 10:40 AM
6	difficulty logging in and interface with NHS digital platforms, constant need to reset password , need for FUP co-ordination calls to verify inputted information	12/9/2021 10:19 AM
7	NA	12/6/2021 11:47 AM

Q8 Is anything currently missing from what is being offered that would be useful to your internal processes?

#	RESPONSES	DATE
1	-Actual dates that are available for apheresis	2/14/2022 8:28 AM
2	Kite Konnect: Ability for pharmacy to approve the order and add the order number for invoicing purposes. This would negate the need to scan the pharmacy paper order and email it to the company to place the order. Both portals: if an order is cancelled or amended by the local team it would be useful to get a message from the portal/company to inform us of this as we have times where the local CAR-T team change things but don't inform us in pharmacy and we need to manage the orders.	12/9/2021 4:31 PM
3	a LIVE booking system on the platform with up to date information on the cells estimated completing date.	12/9/2021 12:42 PM
4	No	12/9/2021 11:11 AM
5	Status notifications to registered email	12/9/2021 10:40 AM
6	No	12/6/2021 11:47 AM

Q9 Does the digital platform offered by the CAR-T manufacturer(s) have the ability to integrate with current systems that your institution or centre has in place?

ANSWER CHOICES	RESPONSES
No, would this be a capability you would like to see from a digital platform?	100.00% 6
Yes, please identify which systems?	33.33% 2

#	YES, PLEASE IDENTIFY WHICH SYSTEMS?	DATE
1	No	12/9/2021 11:11 AM
2	not fully	12/9/2021 10:19 AM

#	NO, WOULD THIS BE A CAPABILITY YOU WOULD LIKE TO SEE FROM A DIGITAL PLATFORM?	DATE
1	No	2/14/2022 8:28 AM
2	Not that I am aware of	12/9/2021 4:31 PM
3	yes	12/9/2021 12:42 PM
4	Yes	12/9/2021 11:11 AM
5	Yes	12/9/2021 10:40 AM
6	yes	12/9/2021 10:19 AM

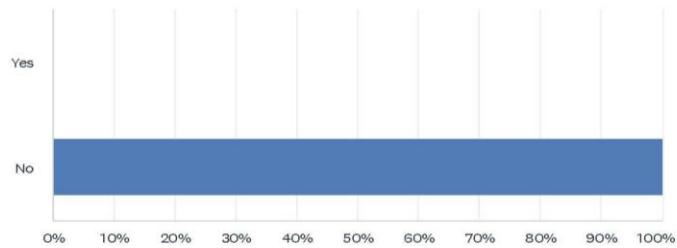
Q10 Does the platform offered by the CAR-T manufacturer have the capability to integrate data and information into the EMR system?

ANSWER CHOICES		RESPONSES
If Yes, what features or attributes are integrated and did you find these features useful		20.00% 1
If No, are there any features or attributes you would like to have integrated with your EMR system?		80.00% 4

#	IF YES, WHAT FEATURES OR ATTRIBUTES ARE INTEGRATED AND DID YOU FIND THESE FEATURES USEFUL	DATE
1	what is an EMR system ?	12/9/2021 10:19 AM

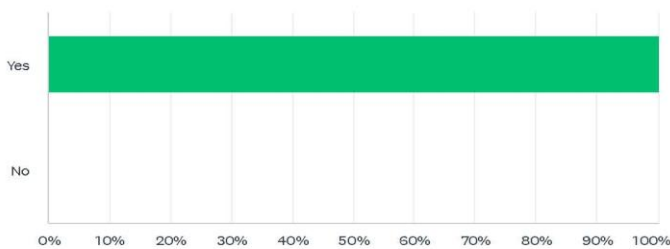
#	IF NO, ARE THERE ANY FEATURES OR ATTRIBUTES YOU WOULD LIKE TO HAVE INTEGRATED WITH YOUR EMR SYSTEM?	DATE
1	No	2/14/2022 8:28 AM
2	Not that I am aware	12/9/2021 4:31 PM
3	no	12/9/2021 12:42 PM
4	Patient ID numbers, access to certificate of release, key product pathway dates	12/9/2021 10:40 AM

Q11 Does the platform offered by the CAR-T manufacturer have the capability to integrate data and information into the CAR-T registry?



ANSWER CHOICES	RESPONSES
Yes	0.00% 0
No	100.00% 4
TOTAL	4

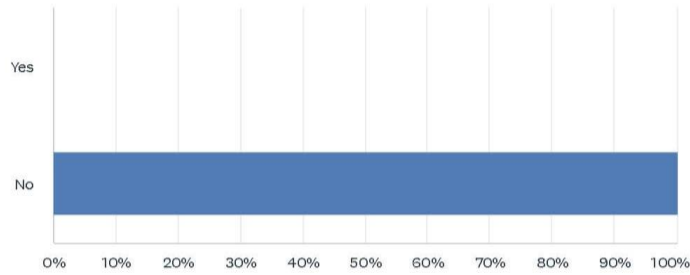
Q12 Did the manufacturer provide any formal training on how to use the digital platform?



ANSWER CHOICES	RESPONSES
Yes	100.00% 7
No	0.00% 0
TOTAL	7

#	IF YES, PLEASE INDICATE WHAT THAT TRAINING INCLUDED	DATE
1	Face to face or virtual training sessions provided for both systems	12/9/2021 4:31 PM
2	virtual training	12/9/2021 12:42 PM
3	HCP training package on portal and product	12/9/2021 11:11 AM
4	Face to face demonstration and dry run	12/9/2021 10:40 AM
5	face to face and virtual support	12/9/2021 10:19 AM

Q13 Do the portals you have used offer any patient-facing digital platforms?



ANSWER CHOICES	RESPONSES	
Yes	0.00%	0
No	100.00%	7
TOTAL		7

Q14 What would you say are the most important operational aspects for a new CAR-T manufacturer to address in order to differentiate from the competition?

#	RESPONSES	DATE
1	- Easy to use	2/14/2022 8:28 AM
2	It would be optimal if all the CAR-T portals were set up the same for consistency. Ease of use to add and schedule patients without needing to email the manufacturer in addition. Ability to track product and have an estimated delivery date for planning purposes. Ability to download QP release documentation from portal is preferable. Ability to approve order and add pharmacy order number to portal for invoicing purposes.	12/9/2021 4:31 PM
3	ease of booking slots, information on availability, up to date information on the cells process status.	12/9/2021 12:42 PM
4	Easy to navigate UI. Ensure systems are reliant on human tasks (co-ordination calls, tocilizumab stock confirmation, enrolment notifications)	12/9/2021 10:40 AM
5	Simplicity and harmonisation across platforms, awareness that users are not necessarily digital/IT experts but most likely clinical nursing staff	12/9/2021 10:19 AM

Q15 What challenges, if any, have you experienced with digital platforms?

#	RESPONSES	DATE
1	Ensuring all required personnel are trained to use portal and have a login.	12/9/2021 4:31 PM
2	as above	12/9/2021 12:42 PM
3	n/a	12/9/2021 10:40 AM
4	interface with NHS IT systems, over complication of systems	12/9/2021 10:19 AM

Q16 If there is an issue with the digital platform (e.g. system error or malfunction) who do you contact to fix the problem and how do you reach out to them?

#	RESPONSES	DATE
1	- Case managers	2/14/2022 8:28 AM
2	Contact the system management team at the manufacturer by email usually in first instance. We have found them very helpful and responsive.	12/9/2021 4:31 PM
3	the company's caseload manager who would escalate it to IT.	12/9/2021 12:42 PM
4	I would contact the company via email or phone	12/9/2021 11:11 AM
5	Email Cell Therapy Manager who refers to the correct team	12/9/2021 10:40 AM
6	The manufacturer , email or phone call	12/9/2021 10:19 AM

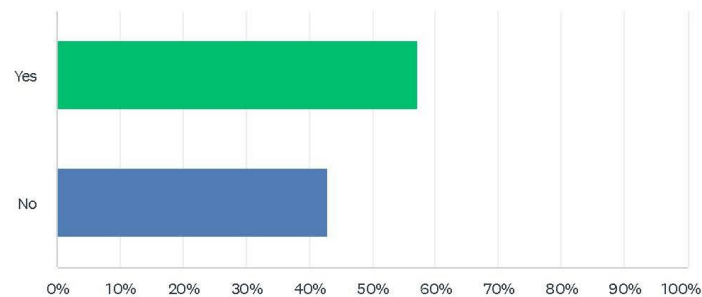
Q17 What would you like to see improved about the interface or software?

#	RESPONSES	DATE
1	as above.	12/9/2021 12:42 PM
2	Integrating with NHS systems	12/9/2021 11:11 AM
3	Universal platform to reduce number of logins as the number of products increase. Standardise processes between companies	12/9/2021 10:40 AM
4	simplicity, ease of access	12/9/2021 10:19 AM

Q18 Please include any further comments on the advantages/disadvantages of using these platforms.

#	RESPONSES	DATE
1	as above.	12/9/2021 12:42 PM
2	n/a	12/9/2021 10:40 AM
3	concerns that as more products enter the market the need for multiple differing platforms will cause undue workload and complication and thus potential error	12/9/2021 10:19 AM

Q19 Would you be willing to take part in a follow up discussion regarding these systems?



ANSWER CHOICES	RESPONSES	
Yes	57.14%	4
No	42.86%	3
TOTAL		7