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Review

# The Cell and Gene Therapy Consortium's Perspective on Harmonizing Data Collection for Patient Enrollment, Therapy Ordering and Scheduling, and Cell Collection

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A B S T R A C T

Established in October 2021, the Cell and Gene Therapy (CGT) Consortium convened with the goal to bring together key CGT stakeholders - manufacturers, treatment centers, regulators, services providers, and ecosystem partners - to gain alignment on process definitions, terminology, challenges, and opportunities for process and data standardization from CGT program start-up and patient enrollment to therapy administration. With the recognition that the number of investigational and commercial cell and gene therapies will scale over the next several years, so will the number of manufacturer-specific processes and solutions (e.g., portals). As a result, this will increase the burden on academic medical centers, community hospitals, standalone clinics, collection facilities, and labs. Healthcare professionals (HCPs) and other industry stakeholders agree that a multiplicity of manufacturer portals with varying data requirements and nomenclature is unsustainable and adds unnecessary complexity - risk, cost, and time - in coordinating patient treatment. Following extensive discussions and multiple stakeholder meetings and interviews, we have developed a manuscript reporting on our activities and conclusions. Through the course of the manuscript, we delineate a framework for defining common principles, terminology, and user experiences for enrolling patients, ordering therapies, and collecting starting material in a standardized way. We also provide substantial background information on opportunities to streamline communications between manufacturing and healthcare organizations from the HCP end-user's perspective.



## INTRODUCTION

As the number of investigational and commercial cell and gene therapies (CGTs) has increased, so too has the number of manufacturer-specific processes and solutions (eg, portals), increasing the burden on academic medical centers, community hospitals, standalone clinics, collection facilities, and laboratories. Healthcare professionals (HCPs) and other industry stakeholders agree that this multiplicity of manufacturer portals with varying data requirements and nomenclature is unsustainable and adds unnecessary complexity—risk, cost, and time—to coordinating patient treatment [1].

To address this specific burden on healthcare institutions, the CGT Consortium, a cross-stakeholder group of 50+ organizations including CGT manufacturers, treatment centers, collection sites, and ecosystem partners (eg, couriers, technology providers) was established to define and recommend common processes, terminologies, and data requirements. If adopted, these recommendations could serve as the foundation for cross-industry alignment and coordination for the design of a universal solution for enrolling, ordering, and scheduling patients for CGTs. Although workflow sequences may differ among manufacturers and therapies, treatment center portals

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should simplify and standardize the user experience while streamlining communication among manufacturers, CGT coordinators, health system users and medical records, and ecosystem partners. Here we report on the progress and observations of the CGT Consortium to date and highlight the contributions and impact from participating organizations. Along with sharing the CGT Consortium's recommendations for needed data standardization and improved communication among CGT stakeholders, this report aims to inspire broader discussion, solicit industry feedback, and drive potential adoption of a universal treatment center portal. Here we present the CGT Consortium's work to date, including:

- Outline of the therapy management process framework, from patient enrollment to cell collection, and common definitions (based on US workflows)
- Current state challenges and the benefits of adopting data and process recommendations (eg, cost savings, time savings, patient safety, minimizing the risk of protected health information data breaches)
- Identification of opportunities for standardization
- Recommendations for change
- The call to action for change.

## CGT CONSORTIUM FRAMEWORK AND METHODOLOGY

Established in October 2021, the CGT Consortium convened with the goal of bringing together key CGT stakeholders—manufacturers, treatment centers, regulators, service providers, and ecosystem partners—to gain alignment on process definitions, terminology, challenges, and opportunities for process and data standardization from CGT program startup and patient enrollment to cell collection. During the biweekly meetings, representatives from each of these stakeholder groups participated in open-forum discussions, facilitated by the Standards Coordinating Body [2], to accomplish the following: (1) define high-level processes that meet the needs of a majority of CGT manufacturers, treatment centers, and CGT modalities; (2) identify potential areas for process and data standardization; and (3) prioritize features and recommendations for a universal treatment center portal to improve interactions across stakeholders.

A subgroup of the CGT Consortium participants formed the Publication Working Group (PWG) to further refine the CGT Consortium's discussion outputs into actionable guidelines and improvements. The PWG sought additional end-user inputs by conducting interviews with CGT coordinators and apheresis nurses to review and confirm opportunities for process and data standardization, as well as users' experiences with treatment center portals, to provide guidance and present the case for adopting a universal treatment center portal. The CGT Consortium outlined a framework and definitions that apply to autologous and matched allogeneic cell therapy products (1 donor to 1 patient).

## CONTEXT AND CASE FOR CHANGE

With more than 2000 clinical trials underway in 2022, the CGT market is expected to see 20 or more Food and Drug Administration (FDA) approvals per year by 2025 [3]. With an Operation Warp Speed pilot for rare diseases on the horizon [4], CGTs are expected to be approved at a much faster rate.

Although this rapid scaling of CGTs theoretically would mean greater patient access, the burden of manufacturer-specific processes and solutions at healthcare organizations will almost certainly inhibit uptake, and hence access, of these newly approved therapies. HCPs at cell therapy collection and treatment centers, including program administrators, nurse coordinators, technicians, and physicians, universally agree that there are too many treatment center portals in use [1]. In the January issue of *Transplantation and Cellular Therapy*, the ASTCT's 80/20 Task Force reports on the cumulative effect of these portals: "As more products are approved, the sheer number of unique IT platforms and variety of communication pathways will eventually overwhelm clinical site staff and can be extremely expensive and time-intensive for each manufacturer to support. This will limit both access to therapy at the site level and patient safety from all angles." [5]. Furthermore, manufacturer-specific solutions result in differences in data collection and nomenclature.

The current situation is vividly burdensome. CGT and nurse coordinators move (or spin) from one manufacturer's required processes and tools to another (eg, "yellow stickies") to help them keep track of separate logins, contact names and phone numbers, and steps and procedures to follow. With different processes and portals come differences in data entry requirements, formatting, and definitions, resulting in persistent calls or emails from manufacturers for clarification, data correction, or data reentry, all of which delay a patient's treatment onboarding and scheduling. Beyond the day-to-day HCP and sponsor end user impact, CGT program administrators—those responsible for establishing, managing, and maintaining programs institutionally and by manufacturer—shared how the duplication of processes and tools impacts program startup costs and speed and contributes overall to unnecessary cost, burden, and risk for even the largest institutions. Figure 1 depicts the current reality, in which HCPs work in a model that emphasizes the requirements of each manufacturer, compared to the future possibility in which HCPs work in a model that facilitates process and data standardization across multiple patients and modalities. This level of data standardization is necessary and sufficient for efficient patient onboarding, product manufacturing, and chain of custody (COC)/chain of identity (COI).

Stakeholders across the industry have expressed that having a single, standardized platform or portal that harmonizes with required data, workflows, and communications, while eliminating duplicative documentation and training, would bring immense value in expediting the time between enrollment and infusion while reducing risk and burden of treating patients with CGTs [1]. Stakeholders also identified risks of entering patient data across multiple portals, as duplicative data entry increases cybersecurity risk and compromises data integrity.

## PROCESS DEFINITIONS AND TERMINOLOGY

The first step of the CGT Consortium's standardization goal was to align on common high-level process definitions and terminology that apply to most autologous and "matched" allogeneic CGT modalities and streamline communications between manufacturing and healthcare organizations. The scope for this publication is the steps from patient enrollment through the collection of the cellular starting material. These processes are represented from the HCP end-user's perspective around onboarding and enrollment of a patient onto a CGT. This group focused primarily on the processes between patient enrollment and Collection and Manufacturing as illustrated in Figure 2.

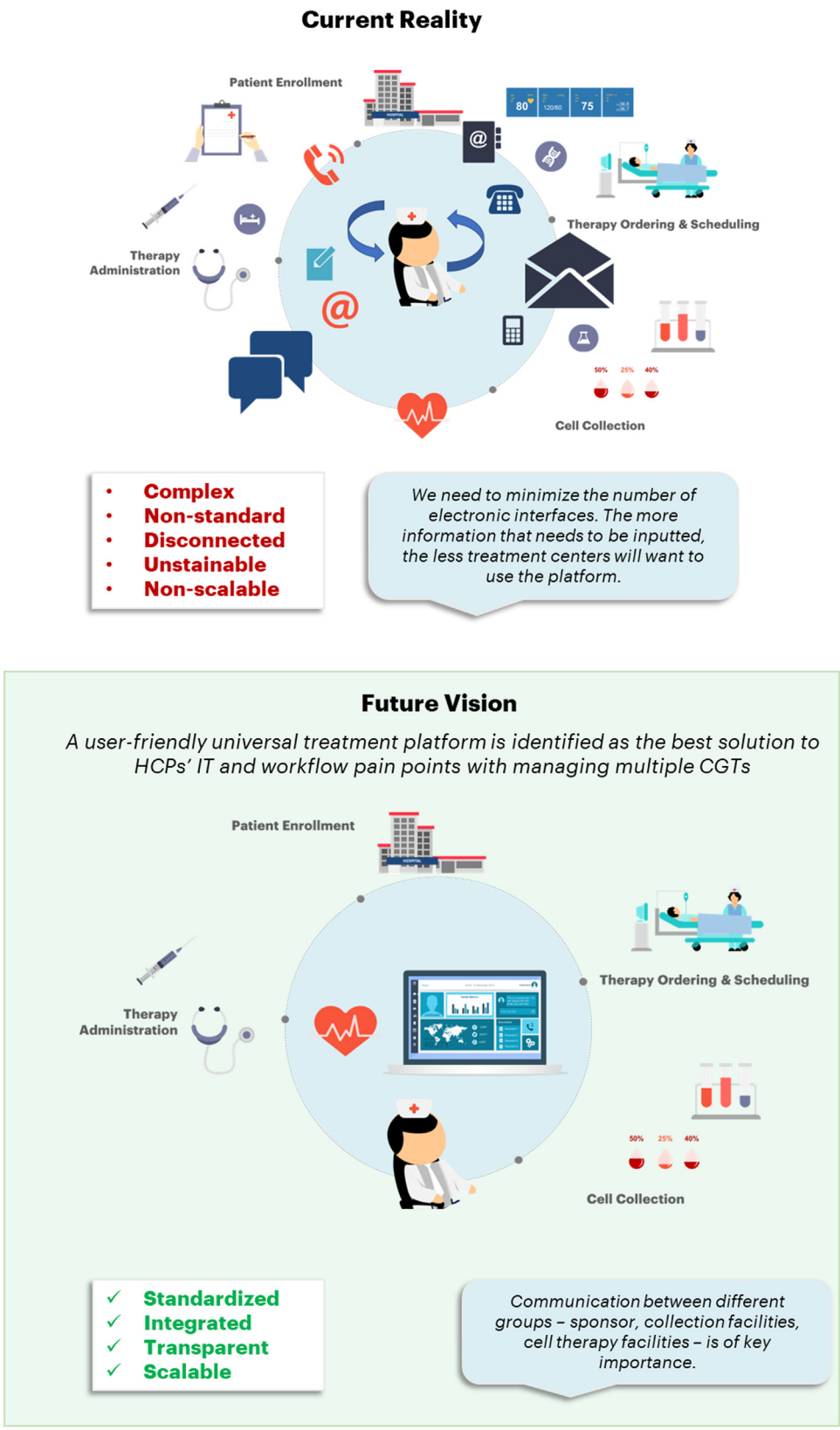


**Figure 1.** Current state versus ideal future state of managing the therapy journey at treatment centers. A majority of HCPs (nurse coordinators, technicians, physicians, etc) at cell therapy collection/treatment centers believe that there are too many treatment center portals available on the market. The multiplicity of interfaces (eg, clinical scheduling portals, commercial ordering portals, communications, and notifications from multiple manufacturers) adds to the burden on HCPs. Priority for HCPs is the impact on the patient, especially when the HCPs must manage last-minute schedule changes. As a result, many HCPs express the importance of having a single, standardized portal that is embedded in their workflows to accommodate multiple patients and multiple modalities while streamlining communication between stakeholders. Communication between different groups—sponsor, collection facilities, cell therapy facilities—is of key importance.

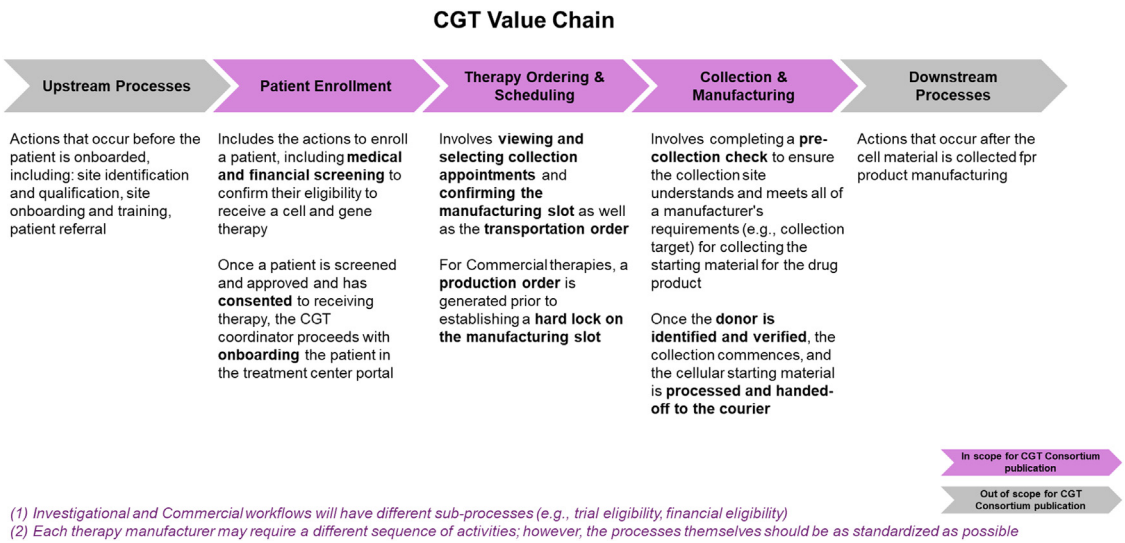


**Figure 2.** CGT value chain terminology and definitions. The high-level CGT value chain presents and defines key steps of the therapy journey, from patient enrollment through manufacturing. To date, the CGT Consortium has discussed the topics of patient enrollment, therapy ordering and scheduling, and collection and manufacturing.

## PATIENT ENROLLMENT

Patient Enrollment occurs after "upstream" activities such as CGT program set-up, contracting, IT, personnel qualification, and training have all occurred. These steps must be completed for each sponsor's therapy at qualified centers. Although out of scope initially for the CGT Consortium scope, it is widely understood that these process steps can benefit from process and data standardization for further treatment center and patient benefits [5].

The following subprocesses occur during patient enrollment:

- Medical eligibility: After being referred for cell and gene therapy, patients will undergo screening activities to ensure they meet specific clinical, health, and genetic requirements to participate in a clinical trial or receive a commercial therapy. For investigational products, these eligibility criteria are set by trial and sponsor. Eligibility for commercial products (US) will be dictated partly by the FDA label but also by the institutional internal policy/practice patterns and insurance coverage thresholds.
- Financial eligibility: For commercial therapies, patients are also screened for their ability to provision funds for the therapy through government insurance, private insurance, or paying out-of-pocket.
- Patient consent: To make informed decisions about their care pathway, patients must be educated about their diagnosis and therapy options, including the implications, risks, and potential side effects. Once they have been provided with this information and consulted with their care team, patients provide written informed consent for research or commercial CGT.
- Patient onboarding: When the patient is ready to be enrolled in a clinical trial or commercial therapy, their data are entered in the portal. (The current state process involves entry into a manufacturer or product-specific portal.) The patient is then assigned a unique identifier, specific to the manufacturer or portal, that helps track their progress through the therapy journey.

Therapy ordering and scheduling, which involves viewing and selecting collection appointments and confirming the availability with the manufacturer, includes the following steps:

- View manufacturing availability: The CGT coordinator reviews the cutoff date for scheduling the collection appointment to coincide with a desired date of product return.
- Schedule and confirm collection appointment: The CGT coordinator selects the collection appointment, and the manufacturer provides the CGT coordinator with confirmation.
- Place a tentative hold on manufacturing dates: The CGT coordinator places a tentative hold on the manufacturing date based on lymphodepletion and infusion dates.
- Place and confirm transportation order: The CGT coordinator then places the transportation order to pick up the collection material. The courier confirms the transportation order and pick-up instructions.
- Production order receipt: The Principal Investigator (PI), prescribing physician, or pharmacy confirms the infusion date, sending confirmation to the manufacturer.
- Confirm manufacturing date: Once the manufacturer releases the work order, the CGT coordinator receives final confirmation of the reserved manufacturing date.

It should be noted that although these steps occur with the manufacturer, they are mirrored by steps at the clinical site in terms of reserving an apheresis facility collection time and date and (for most centers) reserving a shipping time with the cell processing lab.

Cell collection involves completing a checklist of items to ensure the collection site meets all of a manufacturer's requirements for collecting the starting material for the drug product. Each step may vary from product to product. The following steps describe the apheresis process:

- Precollection checks: Typically, the manufacturer provides a checklist with requirements and instructions.
- Donor identification and verification: The donor or patient must be verified, which initiates the COI used for the label on the collection bag. There are typically 9 or 10 COI/COC checks throughout the collection process, in addition to donor identification number (DIN) and product verification. The DIN is a globally recognized unique identifier affiliated with the collection of cellular material and typically the manufactured drug product as well.

- Collection target identification: The manufacturer provides the collection target, which may be presented as a volume or cell count.
- Cellular starting material collection: Donor or patient cells are collected according to product specifications and collection center standard operating procedures (SOPs). Once collection is complete, the apheresis nurse logs the cell count or volume into the treatment center portal.
- Cellular starting material processing: Some drug products require processing of the collected cells prior to packaging, such as dilution, formulation, and/or cryopreservation.
- Handoff to courier: Once the collection material has been inspected, labeled, and packaged in the appropriate shipping container, the sample is transferred to the courier.

The CGT Consortium acknowledges that although the workflow steps should be standardized, the sequence of these steps may differ among manufacturers and treatment centers.

## COMMON PROCESS AND DATA STANDARDS: RECOMMENDATIONS

A universal treatment center portal framework will establish common principles, terminology, and user experiences for enrolling patients, ordering therapies, and collecting starting material in a standardized manner, as supported by the ASTCT through the 80/20 Task Force. The use of common terminology and processes as discussed in the previous section will be necessary in the design of a universal treatment center portal solution.

As shown in Figure 3, our design of a universal treatment center portal focused on standardizing the baseline data principles and user experience for treatment center staff. When users first interact with the portal, they should be able to log in with one password to access appointments for various manufacturers' therapies. We received overwhelming feedback from coordinators, nurses, and other treatment center personnel that portals should be as simple and streamlined as possible and only require information that is critical for manufacturing and maintaining COI/COC. Because each step requires verification for completion, the portal also should provide clear instructions that guide the user throughout the e-signature process to ensure that all data are entered correctly.

During patient enrollment, the CGT coordinator completes the following tasks in the treatment portal:

- Enter patient identification information.
- Enter physician or principal investigator information (principal investigator for investigational therapies only).
- Verify patient's pretreatment eligibility screening.
- Verify patient's prior authorization (commercial therapies only).
- A unique patient identifier is assigned after the prior enrollment steps are completed.

To enable communication with the appropriate stakeholders throughout the process, a contact list for site staff also may be entered at the time of patient enrollment to ensure that emails and notifications reach the proper individual in a timely manner.

It also should be noted that patients' medical history records reside in the electronic medical record and should not need to be reentered into the portal. Ultimately, the universal portal should be linked to the electronic medical record to pull key medical information and eliminate duplicative data entry.

For commercial therapies, the portal should enable workflow configuration for the prior authorization process, because this is handled differently by each manufacturer. The unique patient identifier format, however, should follow a common format among manufacturers Table 1.

During therapy ordering and scheduling, the CGT coordinator performs the following steps (steps may vary by product):

- Check manufacturing slot availability
- Schedule collection appointment
- Confirm manufacturing slot and waitlist manufacturing slots
- Receive appointment reminders and notifications
- Place and confirm transportation order
- Receive purchase order confirmation.

For ease of use, coordinators should be able to access slots for all their qualified therapies in one place with a single sign-

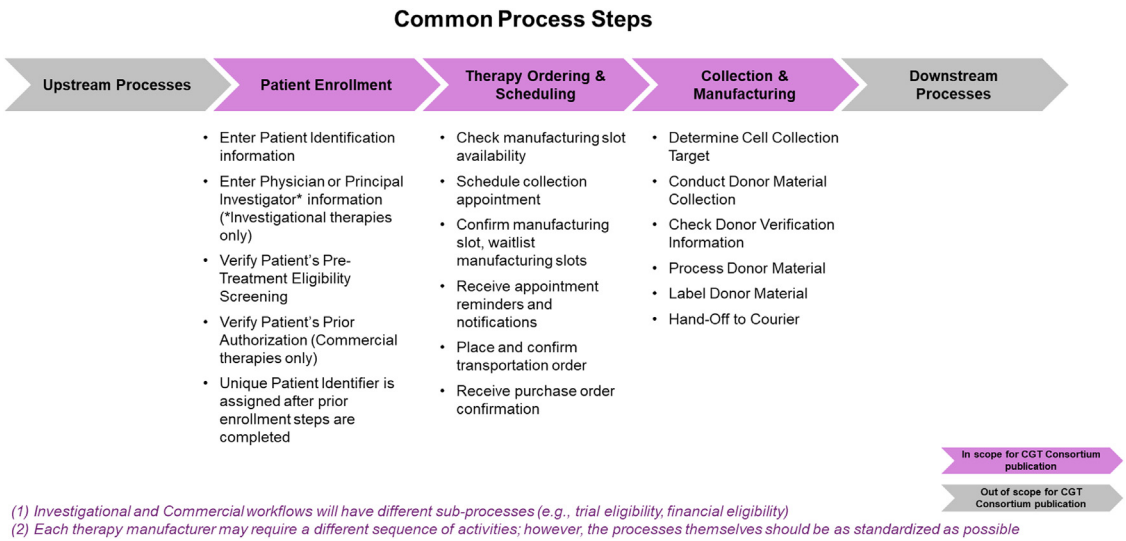


**Figure 3.** CGT value chain common process steps. For each stage of the CGT value chain, there are common process steps that HCPs follow when entering data into the treatment center portal.

**Table 1**
Patient enrollment process steps, common data considerations.

| | Common Data Fields | Optional / Flexible Data Fields | Rationale |
|---|---|---|---|
| **Enter Patient Identification Information** | • Patient name (prefix/suffix, first, middle, last)<br>• DOB<br>• MRN of clinical institution<br>• Disease type and stage/status<br>• Biomarker (gene therapies) | • Physiological data (weight)<br>• Patient contact information<br>• Address; zip/postal code | • Certain regions or treatment centers use different secondary identifiers for patient information<br>• Disease type and status may include stage of remission<br>• Insurance eligibility is based on disease type & status<br>• Portal should capture minimum data for COC & mfg.<br>• Weight should be captured on the day of collection for higher accuracy<br>• Patient address is collected for travel & lodging and co-pay purposes<br>• Patient disease type and stage/status is used when drug product treats multiple indications<br>• Patient contact information to be provided only upon patient clearance<br>• MRN maps to all of a patient's procedures, including apheresis |
| **Enter Treating Physician / Principal Investigator Information** | • Name (prefix/suffix, first, last)<br>• Title at institution<br>• Organization/Institution<br>• Specialties<br>• Contact information (phone, email)<br>• Country<br>• National Provider Identifier<br>• REMS training status | • State of License (US only) | • May provide contact information for referring physicians as a point of reference |
| **Therapy Coordinator Information** | • Name (prefix/suffix, first, last)<br>• Title at institution<br>• Organization/Institution<br>• Contact information (phone, email)<br>• Country | | • Therapy coordinators must be able to receive notifications and alerts |

(*continued*)

**Table 1** (*Continued*)

| | | | |
|---|---|---|---|
| **Check Pre-Treatment Eligibility Screening** | • Pre-treatment eligibility attestation | • Eligibility checklist items (vary by manufacturer & therapy) | • Include standardized baseline questions; leave blank if N/A |
| **Check Prior Authorization (Commercial Only)** | • Prior authorization status (Approved, Pending, Not Approved) | • Checkbox that PA is obtained for patient | • PA & timing will vary by manufacturer, payer, and/or therapy indication (PA may not happen during patient enrollment)<br>• Configurable based on institution's workflow |
| **Payment and Reconciliation of Purchase Orders (Commercial Only)** | • Purchase order status (Paid, Pending, etc.) | • Specialty distributor ID (US – Commercial) | • Streamline reimbursement process for costs to deliver therapy between treatment centers, manufacturers, and distributors<br>• Each manufacturer's process differs based on distributors, use of multiple identifiers, and timing of entry |
| **Enter Clinical Trial Number (Investigational Only)** | • Clinical trial number | | |
| **Assign Unique Patient Identifier Number** | • Assigned patient / subject ID # | | • Auto assigned after successful patient enrollment (differs by institution and clinical vs. commercial workflows)<br>• Treatment center portal would have a universally unique patient identification number that is independent of the manufacturer and product<br>• Could also be used to assign clinical trial ID # |

on. Typically, the quantity of slots per manufacturer is presented in a month-by-month view for each therapy. The portal also should provide the ability for treatment centers to waitlist for newly available appointment slots in the case of a cancellation. Slot availability should take into consideration the collection center's capacity, in addition to the manufacturer's schedule and available capacity.

Notifications and alerts between the manufacturer and treatment center should be tailored to specific user profiles in the portal. For example, CGT coordinators should be alerted to any new or outstanding production orders, in addition to any changes to the final product delivery dates (because this may impact when the patient receives their therapy). These notifications should leverage a standard template and be automated, whenever possible. From a product tracking perspective, a consistent patient identifier should be used throughout the ordering process.

Although manufacturers may use different third-party vendors, these third-party logistics systems should be integrated with the treatment center portal to streamline ordering and demand planning Table 2.

During cell collection, the apheresis nurse completes the following steps in the portal before transferring the collected cells to the stem cell lab for processing (steps may vary by product):

- Determine cell collection target (based on manufacturer's instructions).
- Apply COI label.
- Conduct donor material collection (DIN assigned at the start of collection).
- Check donor verification information.

The cell lab then performs the following steps to process the collected materials:

- Process donor material
- Label donor material
- Handoff to courier.

**Table 2**
Therapy ordering and scheduling process steps, common data considerations.

| Process | Common Data Fields | Optional / Flexible Data Fields | Rationale |
|---|---|---|---|
| **Check Manufacturing Slot Availability** | • Mfg. slots (quantity, time(s), date(s))<br>• Final product delivery dates<br>• Number of slots per month per therapy<br>• Dates available<br>• Days of the week for collection scheduling<br>• Collection (aphe) center available slots | | • Treatment centers need clear visibility into which dates are available and when the product can be delivered to the patient<br>• Treatment centers should be able to access slots all in the same place<br>• Final product delivery date is based on lead time<br>• Slot allocation differs by manufacturer and region (e.g., competitive, batting order)<br>• For each treatment site: Quantity of slots visible per month per therapy (updated once a slot is booked)<br>• Also need to confirm collection center availability (collection site may be separate from treatment site) |
| **Schedule Collection Appointment** | • Collection date & location<br>• Final product delivery date<br>• Final product delivery location | • Lymphodepletion date (CAR T)<br>• Pick up date (if different than aphe date) | • Collection date may or may not correspond to manufacturing date (depending on fresh or frozen aphe) |
| **Confirm Manufacturing Slot** | • Portal automated notification | | • Email notifications can be used as secondary communication<br>• Alerts should be action items assigned to specific people |
| **Waitlist Manufacturing Slots** | • Notification of available slot<br>• Date and time | | • Manufacturers send notification to treatment centers when new slots become available<br>• Time-limited correspondence; if one site misses deadline to claim slot, manufacturer asks another site |
| **Receive Appointment Reminders and Notifications** | • Purchase order due date<br>• Approval for patient travel and lodging | | • Alert treatment centers when slots are cancelled or updated<br>• Communicate to treatment centers when product return dates are changed, reasoning behind timing change, and |

(*continued*)

**Table 2** (*Continued*)

| | | | |
|---|---|---|---|
| | | | schedule impact (e.g., rebooking of line placements, chemotherapy infusion dates, hospitalization admission dates, etc.)<br>• PO date is a few days in advance of collection date |
| **Place & Confirm Transportation Order** | • Date<br>• Pick-up times<br>• Pick up time limitations<br>• Expiration times (shippers, product) | | • Some products have required pick-up times to accommodate shipping times<br>• 3rd party logistics should be integrated with treatment center portal for ease of ordering and demand planning<br>• Shipping address is provided in therapy contract<br>• Pick-up and drop-off locations should be auto-populated |
| **Receive Purchase Order Confirmation** | • Automated confirmation of PO receipt<br>• Date of receipt<br>• PO number<br>• Notice of outstanding PO (reminder)<br>• Patient ID | • Product ID<br>• Enrollment ID | • Varies by manufacturer; once submitted, automated email confirms receipt<br>• Occurs after authorization request is provided by insurance<br>• Some manufacturers use patient ID, others use enrollment ID |

Although cell collection SOPs are defined by the collection site, manufacturers should provide detailed collection checklists with clear instructions on reporting (eg, number of decimal points to report) as well as reference target values. The collection site should follow labeling standards defined by the International Council for Commonality in Blood Banking Automation [6]. The manufacturer should provide support to the cell lab to coordinate cell collection pickup with the third-party logistics company Table 3.

We acknowledge that business and technical flexibility are critical to the widespread adoption of a universal treatment center portal. Workflows may differ among institutions, therapies, and geographies, and the CGT Consortium emphasized required configurability of certain aspects of the treatment center portal to future-proof and accommodate the rapid diversification of CGTs available on the market.

## BENEFITS OF ADOPTION

Standardizing workflow requirements will further ease the burden of many downstream processes. A universal treatment center portal will provide a user-friendly interface and workflow facilitation. To drive industry-wide adoption, we must engage with all involved stakeholders: manufacturers (the sponsors), collection and treatment center personnel (the end-users), payers, regulators, industry advisory groups, and patients.

The decision makers who will lead these efforts must be engaged from a design and investment perspective and acknowledge proprietary interests where they exist but eliminate unnecessary variations in processes when not critical. Manufacturers need to take the lead in investing in the universal solution—specifically the procurement, commercial, and supply chain stakeholders. The timing of universal treatment center portal availability on the market for clinical and commercial therapies can impact manufacturers' willingness to adopt. Manufacturers with marketed CGT products may already have bespoke portals and do not have an immediate need to change portal solutions, whereas first-time commercial manufacturers may need a portal before the universal solution is available or fully configured. In addition, heightened concerns about competition also may discourage manufacturers from subscribing to the solution, and it is likely that manufacturers are waiting for a "first mover" to test the waters with the new solution before wide adoption can occur.

To drive adoption among manufacturers, we need to emphasize the savings in time and costs (technology maintenance, resources, opportunity costs) provided by using a universal treatment center portal versus a bespoke portal. Subscribing to a standard solution also will make manufacturers' products more feasible for adoption at treatment centers while supporting collection sites in providing higher-quality starting material for CGTs. For manufacturers entering the market, joining the standardization effort ensures the adoption of industry best practices.

**Table 3**
Cell collection process steps, common data considerations.

| Process | Common Data Fields | Optional / Flexible Data Fields | Rationale |
|---|---|---|---|
| ***Optional:*** **Conduct Pre-Collection Checks** | • Patient name<br>• DOB<br>• DIN<br>• Label check verification | | • Info already captured in EMR<br>• Process defined by site SOP<br>• Treatment center generates DIN |
| **Determine Collection Target** | • Cell collection target (volume, # cells, etc.) | • Collection target specifications | • The cell collection target (e.g., volume, number of cells, etc.) will vary by manufacturer and therapy<br>• Information is also presented in collection order from manufacturer<br>• Part of SOPs for therapy |
| **Apply COI Label** | • COI Number | | • COI label generated by manufacturer and applied at the start of collection at the apheresis center<br>• Manufacturers map COI to DIN |
| **Conduct Donor Material Collection** | • Collection checklist*<br>• Leukopak volume<br>• Collection date<br>• Collection time, time zone<br>• Number of sample vials<br>• Dilution factor<br>• White blood cell (WBC) count<br>• Hematocrit (HCT) count<br>• Platelets (PLT)<br>• Cryopreservation date<br>• Cryopreservation time, time zone<br>• Cryo bag ID<br>• Cryo bag volume | • Special instructions (e.g., extra materials to collect, volume) | • Manufacturers should specify what data they need collection centers to report and how to report values (e.g., consistency on reporting volume units and rounding specifications)<br>• Collection of information<br>• *Manufacturers should provide “collection checklist” with collection instructions and reference values |
| **Check Donor Verification Information** | • DIN<br>• Donor weight (lbs./kg.)<br>• RN check sign-off verification<br>• Stem cell lab sign-off verification | • Secondary data for patient / donor (e.g., middle name) | • For reporting weight, should have ability to convert lbs. to kg.<br>• Ability to scan DIN without manual data entry (trailing equal signs, zeros)<br>• Each institution may require different levels of nurse verification checks (two RN check is best practice)<br>• PHI is cleared to be used on the labels as long as it’s covered in informed consent<br>• Universal treatment center portal should map |

(*continued*)

**Table 3** (*Continued*)

| | | | |
|---|---|---|---|
| | | | COI to patient PII and DIN; portal should also capture MRN for nurses to search for patients |
| **Process Donor Material** | • Manufacturer's order instructions | | |
| **Label Donor Material** | • Shipment address<br>• DIN<br>• COI<br>• DIN only if re-infusion NOT required | • Labeling instructions differ by manufacturer | • Labeling standard in development (ISBT 128); some centers are already required to follow ISBT 128<br>• Streamline labeling process across manufacturers |
| **Hand-Off To Courier** | • Sign-off confirmation of transfer between aphe unit and cell lab<br>• Package contents<br>• Sender ID<br>• Handling instructions<br>• Recipient ID | | • Waybill handled by stem cell lab<br>• CGT Coordinator at HCO works with manufacturer to arrange courier scheduling |

Although manufacturers may opt to implement only the universal treatment center portal's single login page to connect to their specific manufacturer or product site, we have observed that the real burden goes beyond the login ID and password. To fully streamline the user experience, the treatment center portal also should standardize basic information essential to onboard patients and therapies, order therapies, and schedule patients (while enabling flexibility, as required by the manufacturer).

Healthcare organizations also can influence manufacturers to adopt the solution, because more standardization will result in greater efficiencies, reduced risk of errors, reduced HCP burden, and future-proofed management strategies. Most importantly, having a well-orchestrated system of updates will reduce the logistical and emotional stress for patients as well as therapy coordinators when treatment plans are put at risk because of schedule changes (ie, when bridging chemotherapy and washout dates are no longer valid).

Administrators, cell therapy clinicians and prescribers, transplantation directors, and the C-suite are needed to provide the "customer" perspective to ensure that the solution addresses the current pain points, thus building a case for manufacturers to invest in a universal solution. This will ultimately lead to higher-quality patient care and can even pave the way for community hospitals to also serve as CGT treatment centers to expand patient access.

From the broader CGT ecosystem, we must engage with payers, accrediting and advisory organizations (eg, Association for the Advancement of Blood and Biotherapies, Foundation for the Accreditation of Cellular Therapy, International Council for Commonality in Blood Banking Automation), and drug authorities/international health ministries. To establish a "universal" solution, we also must address country-specific legal and regulatory requirements. For instance, these regulatory restrictions should influence how patient data are protected, provisioned, and shared between entities (eg, General Data Protection Regulation [EU]).

## CALL TO ACTION AND CONCLUSION

The CGT Consortium determined that standardization of the portal used for communication between healthcare providers, manufacturers, and ecosystem partners is feasible and would greatly benefit the advanced therapies field. Although multiple options for standardization were discussed, some of the greatest challenges were in the ability to handle communication around changes that may occur throughout the collection and manufacturing process, from therapy ordering and scheduling through cell collection, including:

- Changes in appointment timing
- Failed manufacturing runs that require rescheduling
- Visibility into open manufacturing slots
- Information about further testing requirements.

To address these challenges, the CGT Consortium identified scheduling and notification as the highest importance for standardization. Solving issues around timing, formatting, data entry, notification of changes, and sharing of information throughout collection and manufacturing would have a positive impact on the field. Having standards for clear and timely communication and notification would enable healthcare providers and manufacturers to more easily communicate and quickly respond to any changes or issues. Rescheduling would occur in a more efficient manner, thus minimizing the number of unused manufacturing slots and maximizing patients' access to therapies.

For the next steps, the CGT Consortium plans to focus on developing a consensus-based standard for scheduling and notification between healthcare providers and manufacturers. Although this article presents initial recommendations, this effort will involve

the creation of a working group to help draft a standard and identify the appropriate standard development organization.

To more quickly move the field forward and execute the vision of a universal solution, we recommend mobilizing manufacturers and third-party platform developers to invest in building and transitioning to the universal solution. Then we must engage treatment centers to influence adoption of the standardized treatment center portal, emphasizing that treatment centers will find it difficult to continue to accommodate new therapies owing to the increasing burden and risk of additional portals.

After focusing on developing the solutions that facilitate patient enrollment, therapy ordering and scheduling, and cell collection, we can then broaden our focus to other aspects of the therapy journey, including:

- Site and end-user management: Addressing cybersecurity risk assessments, handling patient data responsibly, and designing portal training to increase proficiencies and efficiencies while reducing human error
- Contracting: Minimizing the time to start up new therapies at treatment centers
- Regulatory oversight: Streamlining the frequency and variations in the internal and external quality audit process to reduce burden on healthcare organizations
- Quality of care: Reducing the time between patient enrollment and infusion and handling adverse events/long-term monitoring.

As we continue to discuss how to standardize additional processes and features, we should ask ourselves 2 questions: (1) is the information that manufacturers require treatment coordinators to enter in the portal critical to manufacturing and patient safety?; and (2) when is this information needed throughout the therapy journey?

From an implementation perspective, the pathway from the industry's current state to the future state will require universal adoption and change management. Ways of working need to be streamlined among internal and external stakeholders at healthcare and manufacturing organizations. We also need to continuously facilitate conversations between HCPs and manufacturers to pressure test our assumptions and determine how to put these decisions into practice. Future discussion also will need to include allogeneic "off-the-shelf" cell therapies and gene therapies, as well as other personalized therapies. This is also a call to action for the broader CGT ecosystem—payers, US and ex-US regulatory bodies, and community cancer centers—to join the discourse through participating in the CGT Universal Treatment Center Portal Consortium and advocating for standardization.

We understand that there is a long road ahead in achieving this ideal state of having a universal CGT treatment center portal. To design a truly global solution, we need to further our engagement with international organizations. Most importantly, we need to accelerate our efforts to stay ahead of the curve as CGTs rapidly enter the market. Any steps we can take to increase efficiencies will reduce patients' barriers to accessing CGT, saving more lives in the long run.

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## APPENDIX: TERMINOLOGY AND DEFINITIONS

- Investigational: refers to therapies under clinical investigation (also referred to as "clinical research trial")
- Commercial: **r**efers to commercially launched therapies (received approval from regulatory body, eg, FDA)

### Abbreviations

- BI = benefits investigation
- BV = benefits verification
- CGT = cell and gene therapy
- COI = chain of identity
- COC = chain of custody
- DIN = donor identification number
- GDPR = General Data Protection Regulation (EU)
- HCO = healthcare organization
- HCP = healthcare professional
- KOL = key opinion leader
- PHI = protected health information
- PI = Principal Investigator
- PII = personally identifiable information
- PO = production order
- PA = prior authorization
- RN = Registered Nurse
- SOP = standard operating procedure
- SSO = single sign on (one password required)

### Roles

- Institution (CGT) coordinator(s): Responsible for scheduling/confirming collection appointments and placing/confirming transportation orders
- Apheresis nurse: Conducts apheresis/cell collection and inputs data in treatment center portal
- Financial advisor: Responsible for financial setup tasks, including checking and confirming BI/BV and submitting the production order
- Pharmacy coordinator: Executes the purchase order with the specialty pharmacy
- CGT program administrator: Responsible for contracting with the manufacturer/sponsor

### Processes

#### Patient Enrollment

- Medical eligibility: Medical eligibility and/or genetic screening activities to determine patient's eligibility for CGT.
- Financial eligibility: Determination of patient's ability to provision funds for the therapy, either through government/private insurer or out-of-pocket. Does not apply in investigational settings.
- Patient consent: Enable patients to understand their diagnosis and treatment options, and implications for each, to make informed decisions on their treatment path. In addition, make decisions about long-term follow-up, data, and services.
- Patient onboarding: Investigational or commercial enrollment of patient to CGT, including the collection of patient data, assignment of a unique patient identifier, scheduling of appointments and/or manufacturing, and determining treatment availability schedule.

### Therapy Ordering and Scheduling

- View available manufacturing dates: Institution coordinator reviews cutoff date for collection based on estimated arrival of drug product.
- Schedule and confirm collection appointment: Institution coordinator selects collection slot, which is confirmed by manufacturer; the slot reservation is then confirmed, and the estimated infusion date is discussed with the patient.
- Place tentative hold on manufacturing dates: Soft hold on lymphodepletion and infusion dates.
- Place and confirm transportation order: Institution coordinator places transportation order for collection and uploads waybill; the courier then confirms the transportation order and pick-up date and location at the collection site.
- Production order receipt: The physician writes prescription (PO) and notifies the pharmacy; the pharmacy then releases the PO to the specialty distributor, who reviews and submits the PO to the manufacturer to generate the sales order.
- Confirm manufacturing date: The manufacturer releases the work order, and the treatment center coordinator receives confirmation of the reserved manufacturing slot.

### Cell Collection Management

- Precollection checks: To confirm collection site readiness (eg, shipping material availability), the manufacturer provides the collection center with a checklist of procedures and requirements for the CGT product.
- Donor identification and verification: Once the patient identification has been verified, the COI is generated by the sponsor; the label is created and placed on the collection bag.
- Determine collection target: The manufacturer provides the collection volume/cell count to meet the cell target.
- Cellular starting material collection: The apheresis nurse collects that starting material and documents the cell count/volume. The COC is initiated at this point; if required, infectious disease marker screening also takes place at this stage.
- Cellular starting material processing: Some processing may occur prior to packaging (eg, application of reagents or treatments for freezing); the cell processing lab inspects the shipping container, packages the product, and generates the shipping and return labels.
- Handoff to courier: The cell processing lab at the collection center transfers the sample to the courier.

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