

# CareDx Inc.

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<b>Architecture</b>	OtrrCare users access the system using an HTML5 browser. The system's web server is .NET based and data resides in an SQL database. The system is open and licensed to the hospital, or client, which offers the client full control over the data. The platform exchanges data using HL7 and CCD/CDA and now FHIR technology is available. The majority of our clients host the database locally, additionally, we have had clients hosted by their EHR vendor. CareDx will be releasing a Software as a Service (SaaS) model in the upcoming year.	
<b>Co launch</b>	2010	
<b>Co length</b>	CareDx was founded in 1998. OtrrCare, a subsidiary of CareDx, has offered digital solutions to track patient health and improve data reporting since 1993.	
<b>Apheresis</b>	<input type="checkbox"/> No	<b>CTL</b> <input type="checkbox"/> No
<b>ISBT</b>	<input type="checkbox"/> No	
<b>IEC</b>	<input type="checkbox"/> Yes	The OtrrCare Cellular module supports the clinical management and data collection for Immune Effector Cell Therapy. Otrr provides for the electronic submission of CIBMTR CTED data via AGNIS. The form 4000 is available for production use, and the forms 4003, 4006 and 4100 are in development for release. The IEC module includes functionality to track and trend Cytokine Release Syndrome and Neurotoxicity post infusion.
<b>IEC Desc</b>		
<b>Workflow</b>	<input type="checkbox"/> Yes	The OtrrCare module is a long-term clinical software system for the management of transplant recipients, and donors. From new patient referral, through all the stages of the transplant continuum, it enables a clinical program to plan, manage, and efficiently track workflow through configurable electronic plans and actions. Donor workflow actions represent typing, or workup activities, and are scheduled via a calendaring component. The donor dashboard is accessible for real-time viewing by the multi-disciplinary team. The system can link a recipient to their list of potential donors, as well as distinguish the "selected" donor from other donors.
<b>Workflow Desc</b>		
<b>Calendar Functions</b>	<input type="checkbox"/> Yes	
<b>Calendar Desc</b>		
<b>Compliance and Quality Desc</b>	<input type="checkbox"/> Yes	CareDx supports a wide ecosystem in transplant management. The XynQAPI module is a tool that organizes activities within a transplant center's quality program, including the interaction between reporting, analysis, and task management. The tool incorporates predictive analytics to assist with patient management decisions. The XynQAPI module is in production use for Solid Organ Transplant programs and under development within Cellular Transplant.
<b>Research</b>	<input type="checkbox"/> Yes	CareDx is committed to the ongoing management of data standards. As a CIBMTR certified AGNIS vendor our solution shares transplant information across databases to facilitate clinical research and outcomes reporting. Since OtrrCare captures and stores a wide range of transplant specific details, research trending and reporting can be supported. Simple clinical trial tables can track individual patient enrollment, or enrollment by trial types and protocol numbers.
<b>Research Desc</b>		
<b>BI</b>	<input type="checkbox"/> Yes	
<b>BI Desc</b>		
<b>CIBMTR forms Supported</b>	<input type="checkbox"/> Yes	The forms currently supported by Otrr include: 2000; 2004; 2006; 2400;2450;2402;2804;2814;2900;2005;2018;2118;2100; & 4000. The following forms are under development for production release: 4003; 4006; 4100.
<b>DBTC data</b>	<input type="checkbox"/> No	
<b>DBTC Desc</b>	Today the OtrrCare system does not have retrieval capabilities built in for Data Back to Center. Full form data storage is found within OtrrCare's workflow and includes query-ability of the forms information.	
<b>RFI</b>	<input type="checkbox"/> Yes	
<b>RFI Desc</b>	The OtrrCare module supports components of the ASTCT RFI's "Program Information Form" and the "Outcomes Data Spreadsheet" is fully supported. Four population lists and five dashboards assist centers in fulfilling the requirements. Primary diagnosis and disease risk data are used according to definitions provided by the ASTCT. Errors and incomplete information must be resolved in order to accurately complete the RFI. Population lists display errors and/or incomplete information.	
<b>Solutions Other Non Solutions Other Area</b>	<input type="checkbox"/> Yes	In addition to Stem Cell Transplantation and Cellular Therapy, CareDx offers solutions in support of Solid Organ Transplantation. Its portfolio also offers HLA typing products, Testing & Post-transplant surveillance products and services.

## Management Science Associates (MSA)

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<b>Architecture</b>	EDITLife Data and Clinical Workflow Management System is a state-of-the-art, web-based application designed to support compliance with FACT and other regulatory standards and guidelines. User-friendly and highly configurable to fit each center's current and future needs, EDITLife seamlessly connects to all hospital EHRs, reducing data entry and errors to increase patient safety and, ultimately, improve patient outcomes. Through automation and integration, EDITLife streamlines cell therapy clinic and stem cell processing lab workflows from referral through post-infusion follow-up. Utilizing built-in intelligence, EDITLife tracks, displays, and reports critical indicators, enhancing a cell therapy program's Quality and other efforts, and ability to improve outcomes.	
<b>Co launch</b>	EDITLife Data and Clinical Workflow Management System was launched at the 2016 BMT Tandem conference.	
<b>Co length</b>	Incorporated in 1963, Management Science Associates (MSA) has been in business for nearly six decades.	
<b>Apheresis</b>	Yes	CTL Yes
<b>ISBT</b>	Yes, EDITLife's fully-integrated module for Stem Cell Processing Labs (LABHero) has ISBT 128 functionality, allowing data capture that adheres to ISBT 128 standards for cellular therapy products.	
<b>IEC</b>	Yes	The EDITLife CAR-T module addresses the specific requirements for Adult and Pediatric Autologous infusions from initial referral through post-infusion follow-ups. The module efficiently manages real-world evidence for regulatory requirements and research. EDITLife's CAR-T module provides CAR-T-specific data capture for CIBMTR forms, CAR-TOX10 tracking, CRS scoring, and Product Persistence tracking.
<b>IEC Desc</b>		
<b>Workflow</b>	Yes	
<b>Workflow Desc</b>		
<b>Calendar Functions</b>	Yes	
<b>Calendar Desc</b>		
<b>Compliance and Quality Desc</b>	Yes	EDITLife is architected to support Quality and Compliance with regulatory standards, including hundreds of FACT's Clinical Program, Marrow Collection Facility, Apheresis Collection Facility, and Processing Facility standards. The many EDITLife features that help centers maintain Quality and Compliance include: Checklists, Donor Selection, BMT Suite, Reports, Inventory, and Protocols.
<b>Research</b>	Yes	EDITLife's Research Study and Patient Study tools track patient activity in any number of research studies.
<b>Research Desc</b>		
<b>BI</b>	Yes	
<b>BI Desc</b>		
<b>CIBMTR forms Forms Supported</b>	Yes	EDITLife auto-populates, electronically submits, supports, and maintains the following CIBMTR forms. HCT Forms: 2000, 2004, 2005, 2006, 2100, 2400, and 2450. HCT and CAR-T Forms: 2018, 2118, 2402, 2804, 2814, and 2900. CAR-T Forms: 4000, 4003, 4006, and 4100.
<b>DBTC data</b>	Yes	Yes, EDITLife retrieves and utilizes DBTC data for legacy data migration purposes.
<b>DBTC Desc</b>		
<b>RFI</b>	Yes	Yes, EDITLife consolidates information to support the ASTCT Request for Information (RFI) template in an easy-to-consume report.
<b>RFI Desc</b>		
<b>Solutions Other Non Solutions Other Area</b>	Yes	In addition to Stem Cell transplantation solutions for Autologous and Allogeneic BMT, Autologous CAR-T, NMDP Prescription for Elsewhere, and Stem Cell Processing Labs (LABHero), EDITLife offers robust solutions for solid organ transplants: Heart, Lung, Heart/Lung, Liver, Kidney, Pancreas, and Kidney/Pancreas.

# STEMSOFT Software, a Division of STEMCELL Technologies Canada Inc.

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<b>Architecture</b>	STEMSOFT applications are a web-based platform that use a Microsoft SQL-Server database supporting on-premise or client administered cloud deployment. A multi-server deployment model is recommended and the application will utilize Active Directory for authentication. Clients communicate with the web server using any compatible modern web browser. As such tablets, desktops, and laptop workstations are supported.	
<b>Co launch</b>	STEMSOFT's first cellular therapy software solution, BMTbase, was launched in 1993.	
<b>Co length</b>	STEMSOFT has been in business since 1993.	
<b>Apheresis</b>	<input type="checkbox"/> Yes	<b>CTL</b> <input type="checkbox"/> Yes
<b>ISBT</b>	<input type="checkbox"/> Yes	
<b>IEC</b>	<input type="checkbox"/> Yes	
<b>IEC Desc</b>		
<b>Workflow</b>	<input type="checkbox"/> Yes	
<b>Workflow Desc</b>		
<b>Calendar Functions</b>	<input type="checkbox"/> Yes	
<b>Calendar Desc</b>		
<b>Compliance and Quality Desc</b>	<input type="checkbox"/> Yes	STEMSOFT applications include numerous tools to assist with quality including support for electronic review of records, quality dashboards and reports, quality reporting, full traceability of all records, audit trails and audit logs, recall management, occurrence management, role-based user permissions and more.
<b>Research</b>	<input type="checkbox"/> Yes	
<b>Research Desc</b>		
<b>BI</b>	<input type="checkbox"/> Yes	
<b>BI Desc</b>		
<b>CIBMTR forms Supported</b>	<input type="checkbox"/> Yes	All AGNIS-defined forms.
<b>DBTC data</b>	<input type="checkbox"/> Yes	
<b>DBTC Desc</b>		
<b>RFI</b>	<input type="checkbox"/> Yes	
<b>RFI Desc</b>		
<b>Solutions Other Non Solutions Other Area</b>	<input type="checkbox"/> Yes	Cell Therapy Manufacturing electronic batch process record and management software and Cord Blood bank manufacturing and management software for both family and public banks.

# stemTrak LLC

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<b>Architecture</b>	stemTrak is locally hosted, it is installed in the client's IT environment. Data stays safe on the institution's servers and under its control. There are no special server requirements, it is installed on standard business class servers (virtual or physical). stemTrak can be installed on Oracle and Microsoft SQL server databases. stemTrak has a robust security model and can be intergrated with enterprise authentication services and provides user-defined roles and permissions to control access to data and functions.	
<b>Co launch</b>	2015	
<b>Co length</b>	Founded in 2005	
<b>Apheresis</b>	<input type="checkbox"/> Yes	CTL <input type="checkbox"/> Yes
<b>ISBT</b>	<input type="checkbox"/> Yes	
<b>IEC</b>	<input type="checkbox"/> Yes	stemTrak has configurable workflows and forms and can support CAR T/Immunotherapy
<b>IEC Desc</b>		
<b>Workflow</b>	<input type="checkbox"/> Yes	
<b>Workflow Desc</b>		
<b>Calendar Functions</b>	<input type="checkbox"/> Yes	
<b>Calendar Desc</b>		
<b>Compliance and Quality Desc</b>	<input type="checkbox"/> No	stemTrak has a Quality Management Module on the roadmap and is scheduled for release late 2020. The module is designed to help programs streamline achieving regulatory and FACT compliance. Some highlighted features of the module will: <ul style="list-style-type: none"> <li>•Personnel competency assessment provides checklists, physician assessment tracking, and written confirmation report</li> <li>•Policy and Procedure reference list for uploading and management of policy and SOP versions</li> <li>•Auditing for audit schedule, manage audit history, manage audit checklists, store audit reports</li> <li>•Deviation management for managing deviation forms/incident reports, link deviations and reports to clinic and lab objects, record root cause analysis and record action plan steps and status</li> <li>•Quality Dashboard for charts, tables, views, queries of data from the program (e.g.. inpatient deaths, readmissions, collections/apheresis, IDM, adverse reactions, infusions by product and donor type, morbidity, mortality)</li> <li>•QM Reports; out of the box outcomes analysis, efficacy reports, deviation reports, audit reports</li> <li>•Quality Management Document Organizer provides an area to organize and maintain QM related documents like ORG charts, facility and safety documents, 3rd party agreements and other related information</li> <li>•Document Management</li> </ul>
<b>Research</b>	<input type="checkbox"/> Yes	
<b>Research Desc</b>		
<b>BI</b>	<input type="checkbox"/> No	
<b>BI Desc</b>		
<b>CIBMTR forms Supported</b>	<input type="checkbox"/> Yes	Form 2900 Revision 1 Form 2450 Revision 2 Form 2100 Revision 2 Form 2006 Revision 2 Form 2451 Revision 1 Form 2455 Revision 2 Form 2200 Revision 2 Form 2300 Revision 2 Form 2018 Revision 1 Form 2118 Revision 1 Form 2004 Revision 4 Form 2005 Revision 5 Form 2400 Revision 4 Form 2000 Revision 4 Form 2804 Revision 5 Form 2814 Revision 1 Form 2006 Revision 4 Form 2814 Revision 2 Form 2900 Revision 3 Form 2005 Revision 6 Form 2400 Revision 5 Form 2402 Revision 1 Form 2450 Revision 4 Form 2100 Revision 4 Form 2018 Revision 3 Form 2118 Revision 3
<b>DBTC data</b>	<input type="checkbox"/> Yes	
<b>DBTC Desc</b>		
<b>RFI</b>	<input type="checkbox"/> Yes	stemTrak has the ability to create standard RFI reports based on the ASTCT format or any other format you would like. Through the stemTrak interface, point of inception data can be captured. From there, stemTrak makes use of the robust query engine and the reporting tool to generate the ASTCT RFI report. Once created, the report can be annotated and stored in stemTrak. stemTrak also allows for tracking the versions of the reports generated, when and who generated it along with who the report was sent to.
<b>RFI Desc</b>		
<b>Solutions Other Non Solutions Other Area</b>	<input type="checkbox"/> No	

# Title21 Health Solutions

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<b>Architecture</b>	Hybrid architecture of web-based and desktop in a single database with all modules natively integrated. Both HIPAA-compliant Private Cloud and On-Premise are available.	
<b>Co launch</b>	2008	
<b>Co length</b>	19 years	
<b>Apheresis</b>	<input type="checkbox"/> Yes	<b>CTL</b> <input type="checkbox"/> Yes
<b>ISBT</b>	Title21 has an integrated and complete Product Inventory Management module to capture all product, processing and quality data in compliance with FACT, ISBT 128 etc.	
<b>IEC</b>	<input type="checkbox"/> Yes	Title21 supports IEC workflows for collection, shipment, return receipt, infusion, reporting and Title21 can also support the manufacturing of IECs
<b>IEC Desc</b>		
<b>Workflow</b>	<input type="checkbox"/> Yes	
<b>Workflow Desc</b>		
<b>Calendar Functions</b>	<input type="checkbox"/> Yes	
<b>Calendar Desc</b>		
<b>Compliance and Quality Desc</b>	<input type="checkbox"/> Yes	Integrated Enterprise Quality Management System: Document Control, Non-Conformance and Deviations, CAPA, Learning and Competency Management, Change Control, QC Testing, Audit, Complaint Management, etc
<b>Research</b>	<input type="checkbox"/> Yes	Title21 EBR supports IND/Novel Cell Processing Development
<b>Research Desc</b>		
<b>BI</b>	<input type="checkbox"/> Plea	Data Analytics, Outcomes Reporting, RFI, Quality and Ad Hoc Reporting
<b>BI Desc</b>		
<b>CIBMTR forms Supported</b>	<input type="checkbox"/> Yes	2804 (Unique ID Assignment Form) 2814 (Indication for CRID) 2400 (pre-TED) 2402 2450 (post-TED) 2451 (Chimerism) 2455 (Selected Post-TED) 2004 (Infectious Disease Markers) 2005 (HLA Typing) 2006 (Infusion) 2000 (Baseline Follow-up) 2100 (100 day Follow-up) 2200 (6 mo to 2 year Follow-up) 2300 (Annual Follow-up) 2900 (recipient death) Disease Specific Insert Forms: 2018 (Pre-HSCT Hodgkin and Non-Hodgkins Lymphoma) 2118 (Post-HSCT Hodgkin and Non-Hodgkins Lymphoma) 4000 (Cellular Therapy) 4003 (Cellular Therapy) 4006 (Cellular Therapy) 4100 (Cellular Therapy) 9000 (Report) 9001 (Report)
<b>DBTC data</b>	<input type="checkbox"/> Yes	July 2020 will be live with Wake Forest Baptist Medical Center
<b>DBTC Desc</b>		
<b>RFI</b>	<input type="checkbox"/> Yes	Adult/Ped Clinical Outcomes, Adult/Ped Survival Outcomes, Program Information
<b>RFI Desc</b>		
<b>Solutions Other Non Solutions Other Area</b>	<input type="checkbox"/> Yes	Electronic Batch Records -(IND\Novel Cell Manufacturing) , Clinical Case Management,, CIBMTR\Agnis reporting , Chain of Identity, Chain of Custody, Data Analytics, Supplies and Consumables Management, Reagent Manufacturing , Kitting , Apheresis/ Collections, ISBT Labeling , Equipment Maintenance and Calibration, HL7 integration with Epic, Cerner, Sunquest and other EHR and LIMS systems, Lab Instrument/Equipment Integration, Quality Management System, Document Control , Learning and Competency Management, Deviation/ Non-conformance and CAPA Management, Change Control, Complaint Management, Audit Management

# WellSky Corporation

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<b>Architecture</b>	Browser-based system; SQL Server backend; asp.net (in the process of moving to angular)	
<b>Co launch</b>	2012	
<b>Co length</b>	40 years	
<b>Apheresis</b>	<input type="checkbox"/> Yes	CTL <input type="checkbox"/> Yes
<b>ISBT</b>	Yes - our system is designed to comply with all relevant industry standards and accrediting organizations	
<b>IEC</b>	<input type="checkbox"/> Yes	The application's flexible platform allows for the configuration of clinical workflows, and laboratory protocols to support novel cell therapies including immunotherapies
<b>IEC Desc</b>		
<b>Workflow</b>	<input type="checkbox"/> Yes	
<b>Workflow Desc</b>		
<b>Calendar Functions</b>	<input type="checkbox"/> Yes	
<b>Calendar Desc</b>		
<b>Compliance and Quality Desc</b>	<input type="checkbox"/> Yes	WellSky offers a Quality and Compliance module which works with our Biotherapies solution to manage documentation creation and updating (i.e. SOPs), staff training and competency, and quality management workflows and processes (i.e. deviation management)
<b>Research Research Desc</b>	<input type="checkbox"/> Yes	Our system is configurable to support data capture specific to clinical trials and institutional specific research studies - this includes both clinical and laboratory / manufacturing data
<b>BI BI Desc</b>	<input type="checkbox"/> Yes	
<b>CIBMTR forms Forms Supported</b>	<input type="checkbox"/> Yes	All CIBMTR forms are available in electronic format in the application. WellSky is AGNIS certified on all forms that are currently available for electronic transmission: 2804, 2814, 2400, 2402, 2900, 2100, 2006, 2000, 2450, 2004, 2005, 4000, 4003, 4006, 4100, 2018, 2118
<b>DBTC data DBTC Desc</b>	<input type="checkbox"/> Yes	Data pullback can be supported through our data migration engine
<b>RFI RFI Desc</b>	<input type="checkbox"/> Yes	The full ASTCT template is auto-populated through our application - this includes program information as well as clinical statistics and outcomes by disease
<b>Solutions Other Non Solutions Other Area</b>	<input type="checkbox"/> Yes	Cell Processing, Biopharma / Regenerative Medicine, Cord Blood and Tissue Banking, Transfusion Medicine, Medications Management, Specialty Pharmacy, Home Health, Hospice, Behavioral Medicine, Skilled Nursing