Castor CDMS | EDC 2023.x.x
21 CFR Part 11 Assessment of Compliance

Document Version: 1.0

I. Subpart A - General Provisions

The purpose of this document is to describe Castor's compliance with the Food and Drug Administration's TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 11, ELECTRONIC RECORDS; ELECTRONIC SIGNATURES
This document applies to Castor CDMS 2023.x.x as internally developed and tested. Castor CDMS | EDC has been designed and developed to be in compliance with 21 CFR Part 11, electronics records, electronic signatures and predicate rules when implemented and controlled effectively by the System User. Castor achieves compliance through a combination of risk assessment, SOP adherence, and by establishing a structured validated system. It is however the System User's responsibility to ensure that the software, as provided, is deployed and used in a manner that is compliant with 21 CFR Part 11. The system includes features such as Security controls through different access permissions, Audit Trails, Electronic Signatures with integrity checks.

Computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection.

System Name:	Castor CDMS | EDC
System Version:	2023.x.x
System Description:	Castor is a cloud-based Electronic Data Capture (EDC) solution, enabling researchers to easily capture and integrate data from any source. The CastorCDMS | EDC platform allows researchers to set up data capture forms, collaborate with colleagues, survey patient's through questionnaires (ePRO) and import, export and analyze their data in a secure, compliant cloud environment, track the study's progress and patient(subject) inclusion through the study's lifecycle, all without elaborate training or technical skills.
Comments:	The current version of Castor CDMS | EDC was evaluated from the URL: http://2023-1.qa.castoredc.org

Definitions

Electronic Record – is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system (refer to 21 CFR Part 11.3(b)(6)). Only records required by an agency regulation (FDA; Food, Drug & Cosmetic Act; or Public Health Services Act) to be maintained for inspection or to be submitted to an agency are considered within the scope of the 21 CFR 11 regulation. Note: a record is not considered to be "created" until it is committed to durable media.
Electronic Signature – is a digital representation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature (refer to 21 CFR Part 11.3(b)(7)). For a signature to be considered an electronic signature under 21 CFR Part 11, it must be executed as the conscious action of the owner with a specific meaning (e.g., approval, release, review).
Computer System – is defined as a configuration of hardware components and associated software designed and assembled to perform a specific function or group of functions. Included in this definition are laboratory instruments, control systems, and computer systems, including hardware, software, peripheral devices, personnel, and documentation; e.g., manuals and Standard Operating Procedures. Third-party application software as well as internally developed application software is also included in this definition.

Regulation Reference – Reference to the specific paragraph in the 21 CFR Part 11 regulations.

System Supplier - Castor system being assessed

System User- Castor's client, sponsor or CRO using the system being assessed.

II. Subpart B - Electronic Records

1.1 §11.10 Controls for Closed Systems

Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and when appropriate the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:

§11.10(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid altered records.

System Supplier	System User
Castor validates each release per internal SOPs. The System was developed using industry standard development tools and methodologies and was conforming to GxP requirements.	Users must assure themselves that the System Supplier has validated the system based on requirements and guidelines when developing and testing the System. Qualification and requalification audits are available upon request based on internal procedures by contacting the Compliance department,

§11.10 (b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.

System Supplier	System User
The System supports the ability to electronically display , export and print in human readable form all data contained within the system. 1.Printing options: - print empty CRF in PDF format: user can select the configurable elements that are to be printed out (helptext, additional info, calculation field templates, calc fields) - print surveys before or after data has been entered - print participant data in PDF format (individual & in bulk): user can select the configurable elements that are to be printed	Responsible for providing copies of records for inspection by the agency.

out (helptext, additional info, calculation field templates, hidden calc fields) 2. Export options - Export data in CSV, excel, SPSS, SAS, CDISC ODM OR zip file format: user can select the configurable elements that are to be printed out (comments, queries, verifications, encrypted fields) as well as choose display options in the printout (value or label) - choose how to export (tree, variable list, variables bulk) - choose which part of the Study to export (entire study of parts of it) - Export structure in XML format: user can choose to include annotations as well as choose which part of the Study to export (entire structure or parts of it)	

§11.10 (c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

System Supplier	System User
For Castor hosted solutions, all data is backed up routinely per established SOPs. Data backups are performed automatically throughout the day. The restore process is tested every 3 months. Castor also follows standards for record retention periods.	Client is responsible for maintaining all study related data and following their own retention policies.

§11.10 (d) Limiting system access to authorized individuals.

System Supplier	System User
Only authorized individuals are given access to specific clinical studies within Castor CDMS | EDC. Castor EDC employs permission and/or role-based user access based on a user's responsibilities within a specific clinical study. The System includes a login mechanism that requires each user to log in with a unique username and password to gain access to the system. Functions such as password requirements are supported by the System. Single Sign-On: Study access can be accomplished using external Identity Provider credentials, allowing users to login to the system. The System servers are housed in a secure, access controlled environment. Only authorized personnel have access to the servers. Castor has SOPs on how to assign system access to authorized personnel. Study access can be limited based on IP-range in addition to requiring mandatory two-factor authentication, at study and/or user level. In addition to our default encryption of data at rest and in transit, an extra application-level encryption layer can be enabled for sensitive data. This uses encryption keys managed off-site by a trusted third-party key management system. Within the application, fine-grained encryption and decryption authorizations can then be granted per study and institute.	Castor EDC employs role-based user access based on a user's responsibilities within a specific clinical study. User is responsible for defining users and roles in the system. Should assign permissions based on role for access to different information within the system.

§11.10 (e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

System Supplier	System User
System has a full audit trail. All information including reasons for change (for clinical data changes), date, time, user, old value and new value is captured in the audit trail. The audit trail is retrievable throughout the record's retention period and is available to the agency for review, inspection and copy.	Responsible for ensuring the vendor maintains the data and associated audit trails retained and available.

§11.10 (f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

System Supplier	System User
The System has been designed to allow the System User to configure workflows that guide the end user through the proper sequence of events. This configuration is possible at form level, per user-role as well as at the level of data points. Allowing access to various actions, parts, features or modules of the system can be easily managed by setting institute level permissions per user or user role.	Responsible for configuring the System appropriately for their intended use.

§11.10 (g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

System Supplier	System User
Only authorized individuals can access and use the system. Castor CDMS | EDC has been designed to require username and password to gain access. If the user has multiple attempts to log in with incorrect credentials, the system will lock that account out. In order to unlock an account, a study admin must take action. The application uses a role based security model to restrict data access only to authorized users. Study admins can add or remove other system	Responsible for configuring the System appropriately.

users, as well as define permissions and roles. Access to individuals parts of the system and or specific functionalities is determined by the level of permissions granted to each user, for each of the available study sites	

§11.10 (h) Use of device (e.g. terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

System Supplier	System User
Castor verifies source of access by the data stored after login in the API response (eg. login attempts, date & time, timezone for the user who is logged in). In addition, to confirm the integrity of the data that is being entered into the CRFs, any device/system used to enter data into our system (outside of keyboard and mouse being tested implicitly throughout the validation) such as a bar code reader, data integration would include some test (within the system directly leveraging the edit-checks) or outside the system through specific test steps (in API connection, error code returns success or failure for the entry).	Responsible for configuring the System appropriately.

§11.10 (i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.

System Supplier	System User
Castor maintains CVs and JDs for staff that develop or maintain the System. They are hired based on education, training and/or experience, and properly trained according to Castor Policies and Procedures. Training records are maintained as per SOP.	It is the responsibility of the company deploying Castor CDMS | EDC for their clinical trial (e.g. Sponsor, CRO) to ensure that their employees developing, maintaining/administering and using the system have the appropriate training, education and experience.

§11.10 (j) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

System Supplier	System User
Castor requires users to accept Terms of Use when setting up a new user account for Castor CDMS | EDC.	Responsible for ensuring appropriate policies are in place and that compliance with those policies are monitored.

§11.10 (k) Use of appropriate controls over systems documentation including:

§11.10 (k) (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

System Supplier	System User
System documentation can only be accessed by authorized individuals. Castor provides an online resource library and Castor Academy for users to have access to Manuals and User Guides with step-by-step instructions on how to get the most out of Castor systems.	Sponsors are responsible for the creation and maintenance of their own documentation that supports the operation and maintenance of the System.

§11.10 (k) (2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

System Supplier	System User
All documentation is electronically version controlled and any alteration is handled via change controls.	Responsible for the change control documents supporting their production environment.

1.2 §11.30 Controls for open systems

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10. as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity and confidentiality.

System Supplier	System User
Only authorized individuals can access and use the system. Castor CDMS | EDC has been designed to require username and password to gain access. The application uses a role based security model to restrict data access only to authorized users. Study access can be limited based on IP-range in addition to requiring mandatory two-factor authentication. In addition to our default encryption of data at rest and in transit, an extra application-level encryption layer can be enabled for sensitive data. This uses encryption keys managed off-site by a trusted third-party key management system. Within the application, fine-grained encryption and decryption authorizations can then be granted per study and institute. Single Sign-On: Study access can be accomplished using external Identity Provider credentials, allowing users to login to the system.	Responsible for configuring the System appropriately.

1.3 §11.50 Signature Manifestation

§11.50 (a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

§11.50 (a) (1) The printed name of the signer; (2) The date and time when the signature was executed; (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

System Supplier	System User
Castor EDC clearly indicates the full name of the signer, date and time of the signature and the meaning/statement associated with the signature for each electronically assigned record. System users can configure the signature statement and configure which users can sign forms by assigning the required 'Sign' right to them;The signature contains the name, email address, date & time	Responsible for configuring the System appropriately.

§11.50 (b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).

System Supplier	System User
This information is logged statically in the audit trail which is displayed in human readable format. The Audit Trail shows all changes that are made to a study, including changes both during building the form and during data entry. At the moment a system user cannot export the audit trail. However, Castor can export it upon request. The signature information is also displayed within the CRF every time a signature is applied to visit (phase), form (step) or a repeating form (report).	Responsible for configuring the System appropriately.

1.4 §11.70 Signature/record linking

Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred to falsify an electronic record by ordinary means.

System Supplier	System User

All data is digitally signed using unique user's credentials. Electronic signatures within Castor CDMS | EDC are uniquely attributable to a single system user based on an individual's unique username and password. The information stored in the Audit trail is static, meaning that the event details cannot be modified or altered in any way, even after some information of the logged user (eg. last name) are changed at a later point	Responsible for configuring the System appropriately and enforcing appropriate policies to prevent reusing or reassign a user's ID.

2 Subpart C - Electronic Signatures

2.1 §11.100 General requirements

§11.100 (a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.

System Supplier	System User
Electronic signatures within Castor CDMS | EDC are uniquely attributable to a single system user based on an individual's unique username and password. Once a signature is added by one individual, no additional ones can be added to the same element, nor can the signature be modified in any way. Audit trail events are created for signature - when applying digital signatures when digital signatures are dropped / removed when the signature statement is created when the signature statement is changed	Responsible for configuring the System appropriately and enforcing appropriate policies to prevent reusing or reassign a user's ID.

§11.100 (b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature or any element of such electronic signature, the organization shall verify the identity of the individual.

System Supplier	System User
Not applicable. System User's responsibility.	System User's responsibility to verify.

§11.100 (c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997 are intended to be the legally binding equivalent of traditional handwritten signatures.

§11.100 (c) (1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.

System Supplier	System User
Not applicable. Castor sent letter regarding electronic systems used internally. This is the System User's responsibility.	Castor is not responsible for documenting the identity of system users. Responsibility for this task falls on the company deploying Castor CDMS | EDC for their clinical trial (e.g. Sponsor, CRO).

§11.100 (c) (2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

System Supplier	System User
Not applicable. Castor is not responsible for this task. This responsibility falls on the company deploying Castor CDMS | EDC for their clinical trial (e.g. Sponsor, CRO)	Castor is not responsible for this task. This responsibility falls on the company deploying Castor CDMS | EDC for their clinical trial (e.g. Sponsor, CRO)

2.2 §11.200 Electronic signature components and controls

§11.200 (a) Electronic signatures that are not based upon biometrics shall:

§11.200 (a) (1) Employ at least two distinct identification components such as an identification code and password.

System Supplier	System User

When a user signs any form for the first time in a session after the login, the user is prompted to enter their "signing credentials" consisting of a username/email and password combination. Subsequent signings during the same session require one piece of information (i.e. password). This works per session, as described. After each session expires (ie log out, inactivity), the process is resumed.	Responsible for configuring the System appropriately.Institute administrators can enforce additional security policies, such as mandatory two-factor authentication or regular password rotation.

§11.200 (a) (1) (i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components: subsequent signings shall execute at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

System Supplier	System User
Castor EDC requires two distinct identification components (User ID/email and password) during the first signing, and only one component (password) for all subsequent signings in the same system session.	Responsible for configuring the System appropriately.

§11.200 (a) (1) (ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

System Supplier	System User
Castor EDC requires two distinct identification components (Username/email and password) for electronic signatures not performed in the same system session. Subsequent signings during that same session only require the use of password.	Responsible for configuring the System appropriately.

§11.200 (a) (2) Be used only by their genuine owners.

System Supplier	System User
This is covered in the Terms of Use agreed to by a user when initializing their Castor CDMS | EDC user account. Electronic signatures can only be used by the individuals with access to a specific study and that have the necessary permissions enabled.	Responsible for configuring the System appropriately and adopting and enforcing appropriate policies e.g. no username/password sharing. This is covered in the Terms of Use agreed to by a user when initializing their Castor CDMS | EDC user account.

§11.200 (3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

System Supplier	System User
Use of an individual's electronic signature would require collaboration of two or more individuals. Either the user would have to provide the password to another user, or the system administrator would have to collaborate with the user.	Responsible for adopting and enforcing appropriate policies.

§11.200 3 (b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

System Supplier	System User
N/A. Castor systems do not support the use of biometrics.	N/A

2.3 §11.300 Controls for identification codes/passwords

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

§11.300 (a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

System Supplier	System User
Each user has a unique user ID and password combination. The username cannot be used for more than 1 single account on each server that Castor provides. CastorEDC is configured so that a strong password policy is enforced as well.	Responsible for configuring the System appropriately.

§11.300 (b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g. to cover such events as password aging).

System Supplier	System User
Users have individual accounts and strong passwords are required. Users are locked out of their account after 10 failed login attempts. Sessions automatically time out after 20 minutes of inactivity. Institute administrators can enforce additional security policies, such as mandatory two-factor authentication or regular password rotation.	Responsible for configuring the System appropriately and adopting and enforcing appropriate policies.

§11.300 (c) Following loss management procedures to electronically de-authorize lost, stolen, missing or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable rigorous controls.

System Supplier	System User
Users have individual accounts and strong passwords are required. Users are locked out of their account after 10 failed login attempts. Sessions automatically time out after 20 minutes of inactivity. Fine-grained access control is managed by the study administrator and authorizations are granted on a per person per institute basis. All access is denied by default, preventing	Responsible for configuring the System appropriately and adopting and enforcing appropriate policies.

unauthorized access to data by other researchers or institutes.	

§11.300 (d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

System Supplier	System User
Users are locked out of their account after 10 failed login attempts. Only authorized study admins can proceed to unlock a locked account.	Responsible for configuring the System appropriately and adopting and enforcing appropriate policies. Institute administrators can enforce additional security policies, such as mandatory two-factor authentication or regular password rotation.

§11.300 (e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

System Supplier	System User
Tokens or cards used to generate identification codes or passwords are not utilized by Castor CDMS | EDC.	Tokens or cards used to generate identification codes or passwords are not utilized by Castor CDMS | EDC.

Revision History

Document Version #	Description of Change	Author	Effective Date
1.0	Initial Release	Alexandra Marinescu	27-MAR-2023

Approval

The signatures below indicate approval of the content of this document.

Product Author	DocuSigned by: Alexandra Marinescu Signer Name: Alexandra Marinescu Signing Reason: I am the author of this document Signing Time: 27-Mar-2023 | 11:51:03 AM CEST 74108D50BFC84FAD8421FCED93143A12
Name and Title	Alexandra Marinescu, Senior Product Owner
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Name and Title	Eugenia Rudzenok, Quality Assurance lead
Compliance Approval	DocuSigned by: Dimitra Christou Signer Name: Dimitra Christou Signing Reason: I approve this document Signing Time: 27-Mar-2023 | 12:55:38 PM EEDT 18CD11A6CACA4A858D7FEBD7AE122C1C
Name and Title	Dimitra Christou, Senior Compliance Specialist

DocuSign

Certificate Of Completion

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Signer Events	Signature	Timestamp
Alexandra Marinescu alexandra.marinescu@castoredc.com Sr. Product Owner Security Level: Email, Account Authentication (Required)	Alexandra Marinescu Signature Adoption: Pre-selected Style Signature ID: 74108D50-BFC8-4FAD-8421-FCED93143A12 Using IP Address: 62.194.176.253 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I am the author of this document	Sent: 3/27/2023 11:50:02 AM Viewed: 3/27/2023 11:50:49 AM Signed: 3/27/2023 11:51:06 AM
Electronic Record and Signature Disclosure: Accepted: 4/26/2021 1:36:52 PM ID: cade113c-ddd5-445e-a9fb-8aaefbb24109		
Eugenia Rudzenok yauheniya.rudzenok@castoredc.com QA Lead Security Level: Email, Account Authentication (Required), Login with SSO	Eugenia Rudzenok Signature Adoption: Pre-selected Style Signature ID: 618646CF-F724-4610-94DB-6E70D3419B06 Using IP Address: 77.248.79.242 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 3/27/2023 11:51:08 AM Viewed: 3/27/2023 11:51:57 AM Signed: 3/27/2023 11:52:56 AM
Electronic Record and Signature Disclosure: Accepted: 6/21/2021 5:09:58 PM ID: f2f9e391-e833-436a-a758-0cf967b1255b		

Signer Events	Signature	Timestamp
Dimitra Christou dimitra.christou@castoredc.com Sr. Compliance Specialist Security Level: Email, Account Authentication (Required)	 Signature Adoption: Pre-selected Style Signature ID: 18CD11A6-CACA-4A85-8D7F-EBD7AE122C1C Using IP Address: 213.16.174.137 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 3/27/2023 11:52:58 AM Viewed: 3/27/2023 11:55:18 AM Signed: 3/27/2023 11:55:42 AM
Electronic Record and Signature Disclosure: Accepted: 1/10/2022 1:38:46 PM ID: 5d96e447-546c-4b04-97b7-efae4b6b5259		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	3/27/2023 11:50:02 AM
Certified Delivered	Security Checked	3/27/2023 11:55:18 AM
Signing Complete	Security Checked	3/27/2023 11:55:42 AM
Completed	Security Checked	3/27/2023 11:55:42 AM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

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