

CLARIO.

SOC 2 REPORT

FOR

ELECTRONIC CLINICAL OUTCOME ASSESSMENT (ECO), DIGITAL PHYSIOLOGY -
(RESPIRATORY AND CARDIAC SOLUTIONS), DECENTRALIZED TRIAL (VIRTUAL VISIT),
GLOBAL SHARED SECURITY SERVICES (GSSO), AND IMAGING SOLUTIONS

A TYPE 2 INDEPENDENT SERVICE AUDITOR'S REPORT ON CONTROLS
RELEVANT TO SECURITY AND AVAILABILITY

JANUARY 1, 2024, TO DECEMBER 31, 2024

Attestation and Compliance Services



Proprietary & Confidential

Unauthorized use, reproduction, or distribution of this report, in whole or in part, is strictly prohibited.

This report is intended solely for use by the management of Clario, user entities of Clario's services, and other parties who have sufficient knowledge and understanding of Clario's services covered by this report (each referred to herein as a "specified user").

If the report recipient is not a specified user (herein referred to as a "non-specified user"), use of this report is the non-specified user's sole responsibility and at the non-specified user's sole and exclusive risk. Non-specified users may not rely on this report and do not acquire any rights against Schellman & Company, LLC as a result of such access. Further, Schellman & Company, LLC does not assume any duties or obligations to any non-specified user who obtains this report and/or has access to it.

Unauthorized use, reproduction, or distribution of this report, in whole or in part, is strictly prohibited.

TABLE OF CONTENTS

SECTION 1	INDEPENDENT SERVICE AUDITOR'S REPORT	1
SECTION 2	MANAGEMENT'S ASSERTION	6
SECTION 3	DESCRIPTION OF THE SYSTEM	8
SECTION 4	TESTING MATRICES	25
SECTION 5	OTHER INFORMATION PROVIDED BY MANAGEMENT	64

SECTION I

INDEPENDENT SERVICE AUDITOR'S REPORT

INDEPENDENT SERVICE AUDITOR'S REPORT

To Clario:

Scope

We have examined Clario's ("Clario" or the "service organization") accompanying description of Electronic Clinical Outcome Assessment (eCOA), Digital Physiology - (Respiratory and Cardiac Solutions), Decentralized Trial (Virtual Visit), Global Shared Security Services (GSSO), and Imaging Solutions system in Section 3, throughout the period January 1, 2024, to December 31, 2024, (the "description"), based on the criteria for a description of a service organization's system in DC section 200, *2018 Description Criteria for a Description of a Service Organization's System in a SOC 2® Report* (AICPA, *Description Criteria*) ("description criteria"), and the suitability of the design and operating effectiveness of controls stated in the description throughout the period January 1, 2024, to December 31, 2024, to provide reasonable assurance that Clario's service commitments and system requirements were achieved based on the trust services criteria relevant to security and availability ("applicable trust services criteria") set forth in TSP section 100, *Trust Services Criteria for Security, Availability, Processing Integrity, Confidentiality, and Privacy* (AICPA, *Trust Services Criteria*).

Clario uses various subservice organizations for cloud hosting, data center hosting, and off-site tape storage services. The description indicates that complementary subservice organization controls that are suitably designed and operating effectively are necessary, along with controls at Clario, to achieve Clario's service commitments and system requirements based on the applicable trust services criteria. The description presents Clario's controls, the applicable trust services criteria, and the types of complementary subservice organization controls assumed in the design of Clario's controls. The description does not disclose the actual controls at the subservice organizations. Our examination did not include the services provided by the subservice organizations, and we have not evaluated the suitability of the design or operating effectiveness of such complementary subservice organization controls.

The description indicates that complementary user entity controls that are suitably designed and operating effectively are necessary, along with controls at Clario, to achieve Clario's service commitments and system requirements based on the applicable trust services criteria. The description presents Clario's controls, the applicable trust services criteria, and the complementary user entity controls assumed in the design of Clario's controls. Our examination did not include such complementary user entity controls and we have not evaluated the suitability of the design or operating effectiveness of such controls.

The information included in Section 5, "Other Information Provided by Clario" is presented by Clario management to provide additional information and is not a part of the description. Information about Clario's management's responses to exceptions noted has not been subjected to the procedures applied in the examination of the description, the suitability of the design of controls, and the operating effectiveness of the controls to achieve Clario's service commitments and system requirements based on the applicable trust services criteria.

Service Organization's Responsibilities

Clario is responsible for its service commitments and system requirements and for designing, implementing, and operating effective controls within the system to provide reasonable assurance that Clario's service commitments and system requirements were achieved. Clario has provided the accompanying assertion, in Section 2, ("assertion") about the description and the suitability of design and operating effectiveness of controls stated therein. Clario is also responsible for preparing the description and assertion, including the completeness, accuracy, and method of presentation of the description and assertion; providing the services covered by the description; selecting the applicable trust services criteria and stating the related controls in the description; and identifying the risks that threaten the achievement of the service organization's service commitments and system requirements.

Service Auditor's Responsibilities

Our responsibility is to express an opinion on the description and on the suitability of design and operating effectiveness of controls stated in the description based on our examination. Our examination was conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants (AICPA)

and in accordance with International Standard on Assurance Engagements 3000 (Revised), Assurance Engagements Other Than Audits or Reviews of Historical Financial Information, issued by the International Auditing and Assurance Standards Board. Those standards require that we plan and perform our examination to obtain reasonable assurance about whether, in all material respects, the description is presented in accordance with the description criteria and the controls stated therein were suitably designed and operated effectively to provide reasonable assurance that the service organization's service commitments and system requirements were achieved based on the applicable trust services criteria. We believe that the evidence we obtained is sufficient and appropriate to provide a reasonable basis for our opinion.

An examination of the description of a service organization's system and the suitability of the design and operating effectiveness of controls involves the following:

- Obtaining an understanding of the system and the service organization's service commitments and system requirements.
- Assessing the risks that the description is not presented in accordance with the description criteria and that controls were not suitably designed or did not operate effectively.
- Performing procedures to obtain evidence about whether the description is presented in accordance with the description criteria.
- Performing procedures to obtain evidence about whether controls stated in the description were suitably designed to provide reasonable assurance that the service organization achieved its service commitments and system requirements based on the applicable trust services criteria.
- Testing the operating effectiveness of controls stated in the description to provide reasonable assurance that the service organization achieved its service commitments and system requirements based on the applicable trust services criteria.
- Evaluating the overall presentation of the description.

Our examination also included performing such other procedures as we considered necessary in the circumstances.

Service Auditor's Independence and Quality Control

We are required to be independent and to meet our other ethical responsibilities in accordance with relevant ethical requirements relating to the engagement, including the Code of Professional Conduct established by the AICPA and the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants.

We applied the Statements on Quality Control Standards established by the AICPA and, accordingly, maintain a comprehensive system of quality control.

Inherent Limitations

The description is prepared to meet the common needs of a broad range of report users and may not, therefore, include every aspect of the system that individual users may consider important to meet their informational needs.

There are inherent limitations in the effectiveness of any system of internal control, including the possibility of human error and the circumvention of controls.

Because of their nature, controls may not always operate effectively to provide reasonable assurance that the service organization's service commitments and system requirements are achieved based on the applicable trust services criteria. Also, the projection to the future of any conclusions about the suitability of the design and operating effectiveness of controls is subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Description of Test of Controls

The specific controls we tested, and the nature, timing, and results of those tests are presented in Section 4 of our report titled "Testing Matrices."

Opinion

In our opinion, in all material respects:

- The description presents Clario's Electronic Clinical Outcome Assessment (eCOA), Digital Physiology - (Respiratory and Cardiac Solutions), Decentralized Trial (Virtual Visit), Global Shared Security Services (GSSO), and Imaging Solutions system that was designed and implemented throughout the period January 1, 2024, to December 31, 2024, in accordance with the description criteria.
- The controls stated in the description were suitably designed throughout the period January 1, 2024, to December 31, 2024, to provide reasonable assurance that Clario's service commitments and system requirements would be achieved based on the applicable trust services criteria, if its controls operated effectively throughout that period and if the subservice organizations applied the complementary controls assumed in the design of Clario's controls throughout that period.
- The controls stated in the description operated effectively throughout the period January 1, 2024, to December 31, 2024, to provide reasonable assurance that Clario's service commitments and system requirements were achieved based on the applicable trust services criteria, if complementary subservice organization controls assumed in the design of Clario's controls operated effectively throughout that period.

Emphasis of Matter

Clario's description of its Electronic Clinical Outcome Assessment (eCOA), Digital Physiology - (Respiratory and Cardiac Solutions), Decentralized Trial (Virtual Visit), Global Shared Security Services (GSSO), and Imaging Solutions system states that reported security incidents from internal or external users are input into the PMS with a priority and assignment to the security queue. The security team addresses and escalates the incident as needed and documents the resolution in the ticket. However, during the period January 1, 2024, to December 31, 2024, no security incidents occurred that would warrant the operation of the aforementioned controls. Because those controls did not operate during the period, we were unable to test, and did not test, the operating effectiveness of those controls as evaluated using trust services criterion CC7.3, which states "The entity evaluates security events to determine whether they could or have resulted in a failure of the entity to meet its objectives (security incidents) and, if so, takes actions to prevent or address such failures.", criterion CC7.4, which states "The entity responds to identified security incidents by executing a defined incident-response program to understand, contain, remediate, and communicate security incidents, as appropriate." and CC7.5, which states "The entity identifies, develops, and implements activities to recover from identified security incidents.". Our opinion is not modified with respect to this matter.

Restricted Use

This report, including the description of tests of controls and results thereof in Section 4, is intended solely for the information and use of Clario, user entities of Clario's Electronic Clinical Outcome Assessment (eCOA), Digital Physiology - (Respiratory and Cardiac Solutions), Decentralized Trial (Virtual Visit), Global Shared Security Services (GSSO), and Imaging Solutions system which are supported by Enterprise Information Technology and Enterprise Security functions during some or all of the period of January 1, 2024, to December 31, 2024, business partners of Clario subject to risks arising from interactions with the Electronic Clinical Outcome Assessment (eCOA), Digital Physiology - (Respiratory and Cardiac Solutions), Decentralized Trial (Virtual Visit), Global Shared Security Services (GSSO), and Imaging Solutions system practitioners providing services to such user entities and business partners, prospective user entities and business partners, and regulators who have sufficient knowledge and understanding of the following:

- the nature of the service provided by the service organization;
- how the service organization's system interacts with user entities, business partners, subservice organizations, and other parties;
- internal control and its limitations;
- complementary subservice organization controls and how those controls interact with the controls at the service organization to achieve the service organization's service commitments and system requirements;
- user entity responsibilities and how they may affect the user entity's ability to effectively use the service organization's services;
- the applicable trust services criteria; and

- the risks that may threaten the achievement of the service organization's service commitments and system requirements, and how controls address those risks.

This report is not intended to be, and should not be, used by anyone other than these specified parties.

SHELLMAN & COMPANY, LLC

Washington, District of Columbia
February 10, 2025