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Gait Velocity (GV)
Globally Standardized Training and Certification Process

2024

STANDARD

Purpose
Minimize Data Variance
Improve Patient, Subject, Public Confidence and Safety

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Gait Velocity (GV)
Globally Standardized Training and Certification Process

DESCRIPTION: As the **Gait Velocity (GV)** Instrument becomes widely accepted and used by healthcare and clinical research professionals internationally, there is a need for global harmonization and standardization in the proper use of the **GV** to improve inter-rater reliability, to provide human subject protection, patient safety and reassure public confidence in the use of the instrument.

DEFINITIONS:

1) **Gait Velocity (GV)** Scientific Instrument used by healthcare professionals to assess patients in neuroscience and other therapeutic areas.
2) ACTIVITY – Package containing the training and certification course modules.
3) MODULE – Container that delivers materials, questions, answers, and other activities to the user's computer or phone screens.
4) COURSE – Container that controls the delivery of the module, including training and certification activities and its controls of competencies.
5) CRP – Clinical Research Professional
6) CRA – Clinical Research Associate
7) GDPR – General Data Protection Regulation, international laws put in place to protect people's personal identifiable information (PII)
8) GDPR/PRIVACY Account – Electronic Account created and owned by the HCP, CRP, or Rater
9) GDPR/Privacy Wallet – Location where participants keep their own personal documents and certificates.
10) PII – Personal Identifiable Information
11) HCP – Healthcare Professional
12) PARTICIPANT – Rater, healthcare, or clinical research professional
13) PM – Clinical Research Project / Trial Manager
14) QA - Quality Assurance
15) RATER – Healthcare or clinical research professional administering the scale.
16) REDI – Regulatory, Equity, Diversity, and Inclusion
17) SCALE – A scientific validated patient, subject assessment, or diagnostic instrument.

RATIONAL FOR STANDARD: As scientific instruments become internationally accepted a quality assurance (QA) control mechanism must be developed to minimize fraud, waste, abuse, and redundancies in the process of documenting competencies of healthcare and clinical research professionals for the following purposes but not limited to:

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1) Reassuring payers that HCPs are providing patients with the best care possible,
2) Reassuring regulatory agencies of the competencies of HCP and CRP,
3) Reassuring clinical research sponsors of the harmonized competencies of their clinical trial raters,
4) Minimize the possibility of Data Variance in clinical trials.
5) Provide government entities with auditable and duplicatable Delivery, Distribution, Implementation and Tracking mechanisms and processes.
6) Improve global patient, subject and public safety.

THE STANDARDIZED PROCESS

The training and certification program is controlled using the following standardized quality assurance (QA) methodologies to help control redundancies, fraud waste, abuse as well as to help sponsors minimize data variance in clinical research programs.

Creating a GDPR / Privacy Account

1) Participant must create their own personal GDPR / Privacy Account to comply with national, international, and multinational process of sharing and tracking personal identifiable information (PII) including, but not limited to, a) certificates of completion and profile information across vendors, providers, and consumers, b)to identify users across platforms, c) to standardize user documents, certificates and PII to reduce gaming, fraud, waste, abuse and limit redundancies across activity providers.
2) Participant must provide proper profile information as requested by the GDPR based System.
3) Participant is identified by the system and placed in a local GDPR Directory where participant can perform the assigned globally standardized activity.

Methodology Assignment of the Activity

1) Healthcare Professional: The activity can be automatically released based on what activity the participant needs to complete.
2) Healthcare Entity: The activity can be released by a manager or local quality assurance individual at the local entity.
3) Clinical Research Entity: The Activity can be released by a clinical research manager, CRA, or PM.

The Training Process

1) First time participants must complete the training module(s) prior to accessing the certification activities.
2) Participants should be able to access the training module an unlimited number of times.
3) Training should be reviewed by healthcare professionals prior to initial or future recertifications.
4) Re-Training needs to be completed after each unsuccessful certification attempt.

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The Certification Process

1) Each Certification activity contains a module with a series of competency questions based on the initial training
2) Once the module has been successfully completed, an electronic certificate is provided to the participant.
3) All participants must begin with the 1st or initial certification activity.
4) Participants should never be assigned the same certification module which has been used in the past. Recertifications should not be repeated to minimize gaming, fraud, waste, and abuse.
5) Participants will have 3 opportunities to successfully complete the certification activity.
6) After the 3rd opportunity, the participant's activity will be electronically locked to prevent gaming the program.
7) A message will appear to the participant that the activity has been locked and to await further instructions.
8) A message will be sent to the customer support desk that participant activity has been locked.
9) The customer support desk will identify the reason why the module was locked and assess the type of action to take.
10) Customer support will identify any process trends and assess whether the participant is possibly gaming the system or needs additional assistance and guidance.
11) Additional instructions will be sent to the participant letting the participant know the trends and completing any additional training, if needed.
12) If the participant is part of a clinical research trial the Support desk will also send the PM an e-mail notification that a participant has been given an additional attempt to certify.
13) The PM can also have control of any additional attempts and whether the participant is or is not allowed future attempts after the last attempt notice, the Trial Support desk notifies the rater and the appropriate department head (i.e. Sites/Sponsors/CRO) for next steps.
14) Any deviations from the above standardized process must be requested in writing from the sponsor and a Deviation Form must be completed and documented. The customer support desk must report the change request to the CEO for approval. New SOP deviation must be created specifically for that exception, filed, and shared with sponsor / PM.
15) The certification is good for a maximum of one year and training can be accessible by the GDPR/Privacy Wallet owner at any time.
16) Additional certifications are to be completed in sequential order 1st, 2nd, 3rd, 4th, etc.
17) The electronic certification will be maintained in the participant's GDPR/Privacy Wallet and will act as a source of truth used for future audit purposes.
18) Each certification document is valid for a maximum of 1 year when used in clinical trials or a maximum of 1 year when used only for healthcare purposes.
19) Globally monitored certificates can be internationally shareable between organizations.

ALIGNMENT WITH REDI: Regulatory, Equity, Data Variance Prevention, and Inclusion.

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Around the world, government organizations have implemented laws and guidelines to boost the participation of different groups in clinical trials, while also focusing on reducing data variance. To help comply with these regulations, certified language translations and dialects have been created, ensuring that healthcare professionals, researchers, and raters can communicate consistently and effectively across different regions. This standardization is key for screening and assessing patients, which ultimately improves public safety.

Whether research is centralized or decentralized, it's crucial to consider factors like location, race, religion, socio-economic background, and political views. All of these elements impact patient participation and adherence in clinical trials.

To stay compliant with these evolving laws and guidelines, the entire process has been translated into various languages and dialects. And it's important to note that the same training and certification requirements apply to all of them, maintaining consistency across the board.

CONCLUSION

The program authors, including but not limited to universities, governments and regulatory agencies need to collect all clinical research trial / healthcare project information in a globally standardized format to improve the use of the instrument, monitor its use to prevent fraud, waste and abuse while improving patient, subject and public safety. The standardized process on this SOP allows the authors to collect and examine the data in standardized format, record trends to improve the program while adhering to regulatory requirements, current and future laws and regulations and improve the monitoring for General Data Protection Regulations (GDPR) globally and Privacy requirements in the US. Therefore, standards on how the healthcare and clinical research industry stakeholders train and certify "must" be followed and monitored internationally accordingly.

DISCLAIMER

NATIONAL, INTERNATIONAL AND MULTINATIONAL PROGRAM DISCLAIMER

Neither the advisory working groups, the universities nor any other individual or entity involved in the development of these globally standardized program, are responsible for any regulatory, privacy, GDPR or legal liabilities, issues or litigations that may arise from the improper use of this program. Anyone using this program, including but not limited to, healthcare professionals, pharmaceutical companies, medical device companies, sponsors, hospitals, research sites, government or any other healthcare or clinical research entities need to follow program standards accordingly. Users of this globally standardized training and certification program, document competencies, the execution, implementation, tracking of inter-rater reliability to minimize data variance, are advised to properly follow standards herein created for this program originally intended for the improvement of patient, subject and public safety globally.

CHANGE HISTORY

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STANDARD

DESCRIPTION	DATE	ACTION	REVIEWED BY
Originated	09-8-2014	Establishment	Steven Cramer, Al Pacino, John Hill
Reviewed	4-3-2016	Creation of GDPR Wallet for Shareable Certificate Storage and PII privacy protection	Al Pacino
Reviewed	12-20-2020	REDI Inclusion	Al Pacino
Reviewed	2-3-2022	No Updates	Al Pacino
Reviewed	2-16-2024	No Updates	Steven Cramer, Al Pacino
Updated	3-28-2025	Updated REDI Summary	Al Pacino, Ryan Clemons

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