

Statement on MedDRA® Data Sharing

The MedDRA subscription agreement includes a number of terms and conditions that must be agreed upon to receive MedDRA from the MSSO. This includes the following:

- The subscription provides access to MedDRA for one year. The subscription must be renewed each year to continue to use MedDRA. Discontinued subscriptions require the removal of MedDRA from the subscriber's IT environment.
- The subscriber may not grant any sublicense nor publish nor otherwise distribute MedDRA to a third party.
- MedDRA may be shared with all members of your organization and their majority-owned (greater than 50%) subsidiaries. There is no limit to the number of copies you may make for use within your organization.

This document is intended to explain further how MedDRA users can properly share MedDRA including MedDRA coded data. There are a number of common scenarios:

Sharing MedDRA with other organizations

- Organizations are encouraged to validate the subscription status of their business partners on an ongoing basis (at least annually) to ensure both parties have an active subscription. This may be done by obtaining your business partner's MedDRA ID, which you can validate via the [MedDRA Self-Service application](#), the subscription validation API, or via the [MSSO Help Desk](#).
- Data may be freely exchanged between current MedDRA subscribers (see Figure 1, Exchange scenario 1), including but not limited to sponsor-sponsor, CRO-sponsor (see Figure 1, Exchange scenario 2), vendor-user, etc. If confirmation is needed regarding the status of a subscription (your own, a partner, or vendor), please use the Subscription Status function of the [Self-Service Application](#) or contact the [MSSO Help Desk](#).
- Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license. For example, when a CRO is performing MedDRA coding for a sponsor company, both the sponsor company and the CRO need to maintain current MedDRA subscriptions (see Figure 1, Exchange scenario 3). This is true

for all cases including when the CRO is performing all data management activities for a sponsor including submitting the data to regulatory authorities.

- Providing MedDRA coded data reports to regulatory authorities does not require a confirmation of the regulator's MedDRA subscription status (see Figure 1, Exchange scenario 4).

Public Hospitals and Clinics

- Public hospitals and clinics that are using MedDRA for non-commercial or non-profit purposes can subscribe to MedDRA or get access to MedDRA through the country's lead regulatory authority or Ministry of Health.

EDC Vendors

- Electronic Data Capture (EDC) vendors also have a responsibility to ensure the sponsor companies/CROs of their software tools are current MedDRA subscribers (see Figure 1, Exchange Scenario 5).
- An EDC vendor may not have to subscribe to MedDRA if they load the MedDRA files provided by a MedDRA subscriber, but they cannot provide MedDRA to any other client and they cannot use MedDRA in the provision of services for their clients (i.e., directly coding or analyzing data on behalf of their clients) without a MedDRA subscription.

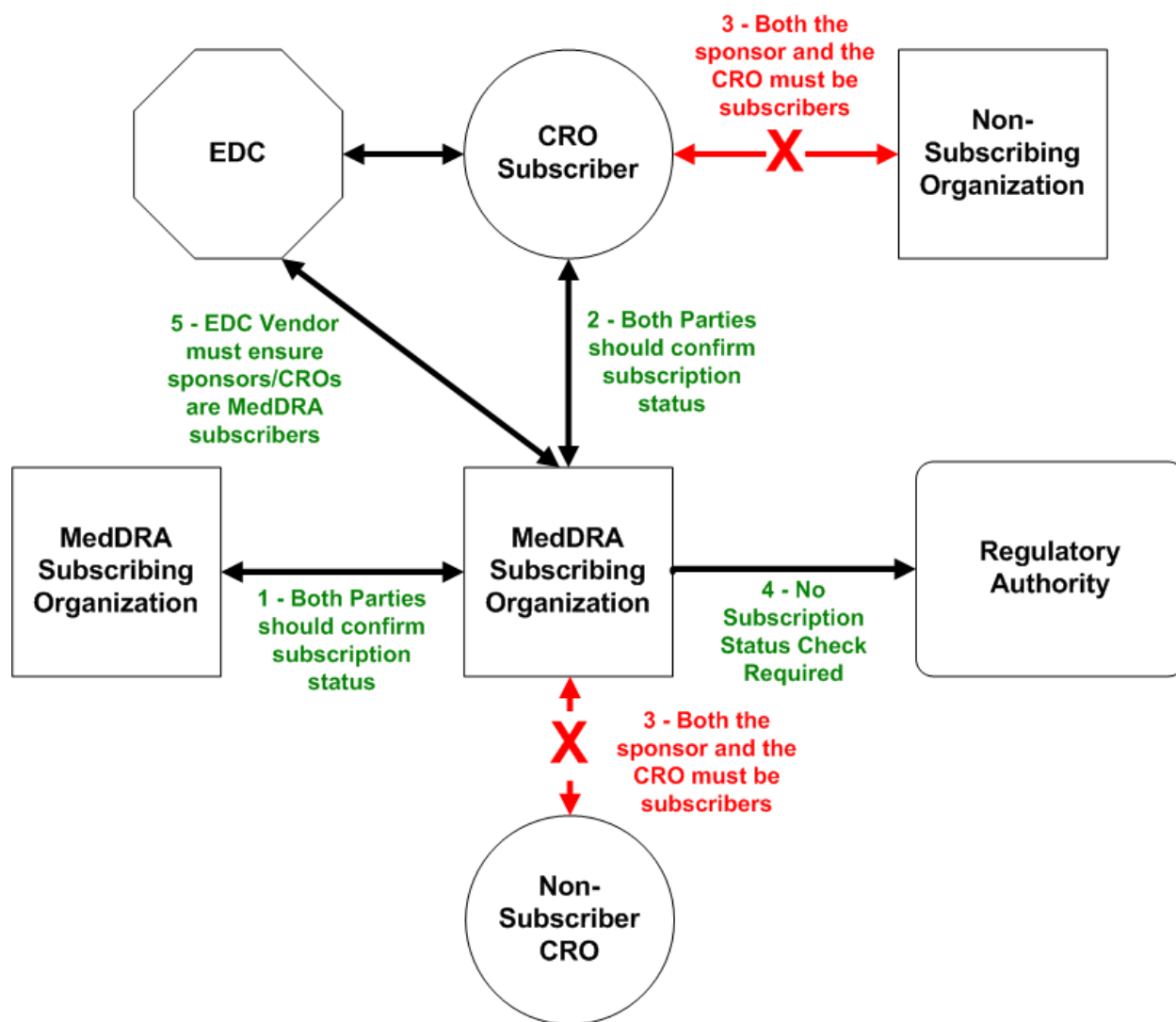


Figure 1 MedDRA exchange scenarios

Note: The boxes in Figure 1 labeled “MedDRA Subscribing Organization” refer in general to any type of MedDRA subscribing organization (e.g., pharmaceutical, non-profit, academia, system developers). CROs and EDC vendors are also valid MedDRA users and are only identified separately in this diagram to identify their unique roles in data transfer.

Sharing MedDRA with Academic Institutions

- In many parts of the world, academic institutions have the right to request data—including MedDRA-coded data—from pharmaceutical companies or related organizations for research purposes. In these situations, the following guidelines apply:

- If the data provided includes MedDRA terms and codes but contains little or no information on the MedDRA hierarchical structure, the academic institution does not need a MedDRA subscription.
- If the academic institution requires access to the MedDRA hierarchical structure (that is, the full or a portion of the MedDRA data files), it must obtain a MedDRA subscription.

Using MSSO Provided Tools

- The same restrictions on sharing MedDRA discussed above apply to MSSO provided tools (e.g., MedDRA Web-based Browser, MedDRA Desktop Browser, MedDRA APIs).
- Providing access to MedDRA tools to an organization that is not a MedDRA subscriber is a violation of the subscription agreement. This includes providing access credentials to MSSO applications (e.g., MedDRA Web-based Browser, MedDRA Desktop Browser) or providing MedDRA data through the MedDRA Application Program Interfaces (APIs) to unlicensed third parties.

MedDRA and Artificial Intelligence

- Use of MedDRA content in conjunction with Artificial Intelligence (AI), including Large Language Models (LLMs) and related technologies, is permitted **only** under the following conditions:
 - The use occurs **internally** within a subscribing organization, or
 - The use involves third-party entities that are also MedDRA subscribers.
- It is a violation of the MedDRA license to use MedDRA content with AI, LLMs, or similar technologies in contexts where **non-subscribing organizations** may gain access to MedDRA content. This includes use in open-source platforms, publicly accessible datasets, or any environment where MedDRA content could be exposed to unlicensed MedDRA users.

- Organizations are responsible for ensuring that MedDRA content remains protected and is not inadvertently disclosed through AI training, deployment, or integration workflows.

MedDRA in publications

- MedDRA text terms may be used in examples, but the examples need to be limited in size (less than 1,000 terms).
- Articles that cite MedDRA should state that “MedDRA® the Medical Dictionary for Regulatory Activities terminology is the international medical terminology developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)”.
- The following acknowledgement statement should appear in articles referencing MedDRA: MedDRA® trademark is registered by ICH.

We hope this information will answer any questions you might have concerning the MedDRA licensing agreement. If you would like additional information, please contact the [MSSO Help Desk](#).

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