

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 in order 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.

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

Sharing MedDRA with other organizations

- Data may be freely exchanged between current MedDRA subscribers (see Figure 1, Exchange 1), including but not limited to sponsor-sponsor, CRO-sponsor (see Figure 1, Exchange 2), vendor-user, etc. If confirmation is needed regarding the status of a subscription (your own, a partner, or vendor), please 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 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 4).

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 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.

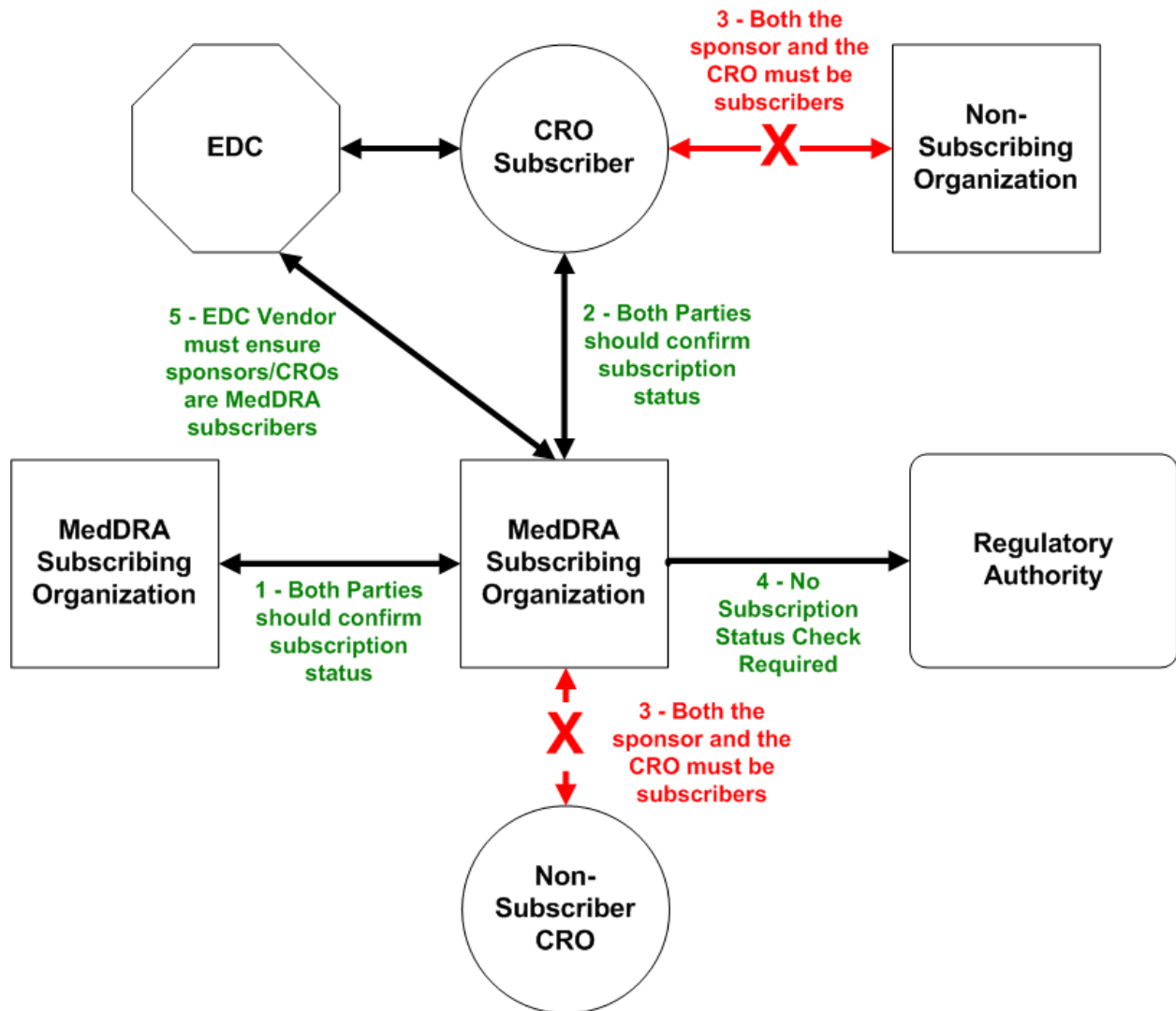


Figure 1 MedDRA exchange scenarios

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.

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 IFPMA on behalf of 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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