Artificial Intelligence (AI) Use and MedDRA Licensing Considerations

As organizations explore ways to integrate Artificial Intelligence (AI) into their workflows, some may consider using AI tools to support MedDRA coding activities. The MSSO offers the following important points to ensure compliance with MedDRA licensing, to protect MedDRA intellectual property rights, and to maintain the quality of MedDRA-coded data:

- **MedDRA is a licensed terminology and must not be shared with unlicensed organizations or software tools.** It may only be uploaded to or used with software tools where that use is authorized under the applicable MedDRA license or falls within the scope of the licensed organization (see more details below)

- **MedDRA must not be loaded into public AI tools**, as doing so could risk exposing the terminology to users who are not licensed, which is a violation of the MedDRA licensing agreement. Some AI platforms may prompt users to upload MedDRA files to improve performance; subscribers should not upload MedDRA into any tool that is publicly accessible.

- **MedDRA may be used within non-public, internally controlled AI tools** operated by MedDRA-subscribing organizations, provided access is restricted exclusively to licensed users within the organization or business partners that are also licensed users. Such use should only be permitted where an appropriate data processing agreement is in place that prohibits the use of MedDRA content or related data for model training, and where the data is not disclosed, transferred, or otherwise made available to third-party sub-processors, unless such sub-processors are expressly authorized and contractually bound by equivalent restrictions. Please see the Statement on MedDRA Data Sharing for more information.

- **AI tools may generate outputs that appear to be MedDRA terms but are not valid MedDRA terminology (i.e., hallucinated MedDRA terms).** MedDRA users should always validate AI-generated coding results against their licensed version of MedDRA. MedDRA content generated or reproduced by an AI tool should not be assumed to be authoritative merely because it resembles official MedDRA terminology. The MSSO accepts no responsibility or liability for errors, omissions, inaccuracies, hallucinated terminology, or other misuse or

misinterpretation of MedDRA arising from the use of AI tools, or for decisions or actions taken in reliance on AI-generated outputs.

- **Organizations are encouraged to share this information internally** to ensure appropriate and compliant use of MedDRA with AI technologies.

Thank you for helping maintain the integrity and proper use of MedDRA. If you have any questions, please contact the MSSO Help Desk at mssohelp@meddra.org.