



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

OFFICIAL

This form, when completed, will be classified as 'OFFICIAL'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Request for a Unique Device Identification (UDI) meeting

Use this form to request a meeting with the UDI Team.

Before requesting a meeting

Consider whether you need a meeting. You may resolve your issue more effectively by:

- visiting the [UDI Hub on the TGA website](#)
- reviewing the UDI guidance on the UDI Hub
- seeking advice from a [regulatory consultant](#).

Purpose of a UDI meeting

A UDI meeting helps applicants understand UDI requirements and the AusUDID.

However, the TGA's UDI Support Team does **not**:

- give advice on non-UDI matters
- evaluate data
- recommend third party data providers.

When a meeting is most useful

Meetings are most useful for:

- AusUDID users who use machine-to-machine submissions
- sponsors or manufacturers with complex medical devices.

How the TGA responds

We respond to requests and, if we decide a meeting is the best option, we will schedule a mutually acceptable time and date.

We may decide that a meeting is not the best option where:

- the issues can be easily resolved without a meeting
- the questions can be answered with existing guidance, UDI Hub content, or a user testing the AusUDID themselves.

We do not generally reschedule or cancel unless there are extenuating circumstances.

Post: PO Box 100, Woden, ACT, 2606 - ABN: 40 939 406 804

Phone: 1800 020 653 - Fax: 02 6203 1605 - Email: UDI@health.gov.au - <https://www.tga.gov.au>

Reference/Publication #

During the meeting

A TGA officer opens the meeting and confirms that:

- the meeting will focus only on the identified issues
- the meeting is not a forum to promote therapeutic goods or company history
- no one may record the meeting in any format.

Our guidance at the meeting is nonbinding and without prejudice. As knowledge evolves over time, the initial guidance we gave at the meeting may become out of date or be superseded.

Submitting this form

Once completed, submit this form to the UDI Support Team at UDI@health.gov.au.

Application details

Please complete the form below.

Applicant

Company

Address

Contact person

Name

Position

Mailing address

Phone

Email

Proposed scheduling information

Proposed date

Please propose a date at least 2 weeks into the future.

Proposed time

Proposed

meeting length

(30 minutes to one hour maximum, unless agreed otherwise)

Once TGA receives your initial completed meeting request, we will consider your request and then advise if it is appropriate for a meeting to proceed or whether the issues can be appropriately addressed via email.

Meeting type

Please note that UDI meetings can only be held over teleconference/videoconference.

The Teleconference/videoconference will be arranged by the UDI Support Team.

Subject matter for discussion

- UDI requirements
- AusUDID requirements
- AusUDID portal submission methods (online, *Australian UDI Bulk Upload Template*)
- AusUDID machine to machine submission methods (HL7 SPL, National Product Catalogue)
- Other (please specify)

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Name			
Signature		Date	

Please ensure that all information set out below is provided with the initial request.

Meeting details

Proposed agenda	Provide your proposed agenda.
Purpose and objectives of this meeting	Provide: <ol style="list-style-type: none"> a. a brief statement of the meeting purpose and objectives b. a description of the issues underlying the agenda c. a summary of the key questions you intend to ask.
List of questions	Group questions by subject (UDI, AusUDID, submission methods). Include a brief explanation of each question's purpose and context.
List of participants	Provide a list of participants, including: <ol style="list-style-type: none"> a. Name b. Title c. Email address.

Please also provide any additional information that may be useful during the meeting, including:

- ARTG details
- Packaging and labelling examples
- UDI record(s).