Data with Integrity: Frequently Asked Questions

- **Who should be submitted to be the primary contact and alternate?**

Ideally the responsible person(s) in your organisation who manages the relationship with SAMED. It should be someone who is familiar with internal business processes and has access to company information or division heads.

- **What is the role of these people? Primary vs Alternate?**

The primary contact's responsibility will be to assign the person(s) responsible for submitting information on behalf of the company and for coordinating with internal departments to ensure that accurate information is provided within deadlines. The alternate contact would be the nominated "second-in-command" in case of unavailability / change of the primary contact.

- **When does the alternate get involved?**

If the primary contact is unavailable for any reason, the alternate contact is required to assume the role of the primary contact.

- **Is the alternate copied on all communications?**

Yes. The alternate contact should always be aware of the status and requirements should need to step in for the primary contact.

- **How do we ensure that alternate and the primary don't over write each other's work?**

Independent login's and user roles in the system will be allocated and an audit log will be kept to track who added what information and when.

- **What areas/categories of data will be collected?**
    o Company information
    o Financial information
    o Employment information
    o Regulatory information
    o Local R & D information
    o Local Manufacturing information
    o Import and export information

- **Who is going to be submitting the data? Who will assign the users?**

Users nominated by and set up by the primary / alternate contact. It is recommended that the assigned users have the related authority and access to information required.

- **How do I choose the relevant user?**

Internal structures will provide you with a guide as to whom to set up as the users, you can use the examples below as a guide:
    o Company information – Primary contact
    o Financial information – Head of finance or authorised person who has access to company sales revenue, turnover and expenditure data

- o Employment information – Head of human resources or authorised person who has access to company employment details including demographics
- o Regulatory information – Person who has access to the company's Medical Device Establishment Licence and Quality Management details, such as a head of regulatory or authorized representative
- o Local R & D information – Head of Product Development or authorised person who has access to company local research and development activities and incentives information
- o Local Manufacturing information – Head of Product Development or authorised person who has access to company manufacturing output, capabilities, and processing data
- o Import and export information – Head of Logistics or Sales or authorised person who has access to company import and export data

- **When will the portal be open to collect data?**

Communication generated by the SAMED portal will advise users by both email and system notifications. SAMED plans to collect or update information twice annually with ad-hoc requests on specific items from time to time as required.

- **How long will the portal be open for submissions?**

This will depend on the nature of the data requested and will be communicated prior to and during the submission phases.

- **What is going to happen to my data?**

Your data will be securely stored in the South African Microsoft Azure (cloud) instance, encrypted and only accessible by yourselves and authorised SAMED representatives. The data will be used in an aggregated format to generate industry specific reports which SAMED will use to inform strategies, decisions and submissions as well as engage with stakeholders.

- **Is the platform POPIA compliant?**

Yes, data storage and access will be managed in accordance with the SAMED POPIA policies made available to all SAMED members.

- **Is the platform secure?**

Yes, both the portal and cloud data storage are set up with best practice security features i.e.
- Strong password requirements
- Regular password resets
- Dormant accounts are deactivated
- The website domain has a security certificate
- Azure platform encryption

- **Who will be able to access the data that I submit?**

The data will be accessible only by the assigned user, the primary contact and SAMED's secretariat. No company will be able to access another company's information.

- **What reports will I be able to access? What is in it for me?**

Participating companies will have access to aggregated reports based on the information that they have provided.

- **Will I be able to edit once I have submitted data?**

Data will be editable for the duration of the submission period.

- **Can I save the data halfway through? What if I lose connection halfway through?**

Yes, the secure portal will allow "auto-save" functionality through secure browser practices, as well as user friendly segmentation of data collection tools to promote regular saving of data as you go.

- **How do I know that my data has been submitted?**

The portal will provide you with regular user prompts, of which (successful) data submission notifications will be included.

- **What happens when I don't remember my password?**

The portal will provide a "Forgot Password" feature with 2 factor authentication. Should you still struggle with this, the portal allows for your company Primary contact to trigger a reset on your behalf.

- **Who do I contact if I am encountering challenges/problems?**

First step: Contact your companies nominated "Primary contact" to troubleshoot the problem
Second Step: Contact the SAMED help desk here: 011 704 2445 / communication@samed.org.za