الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – G 019

Guidance on Saudi Food and Drug Authority Policy for Engagement with Patients

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SFDA Policy for SFDA Engagement with Patients

Policy Goal

The SFDA seeks to engage with patients to ensure the inclusion of patient input into regulatory decision-making, improve patient understanding of the role of SFDA, and to enhance communication between SFDA and patients on the risks and benefits of medical devices and drugs.

Patient Engagement Defined

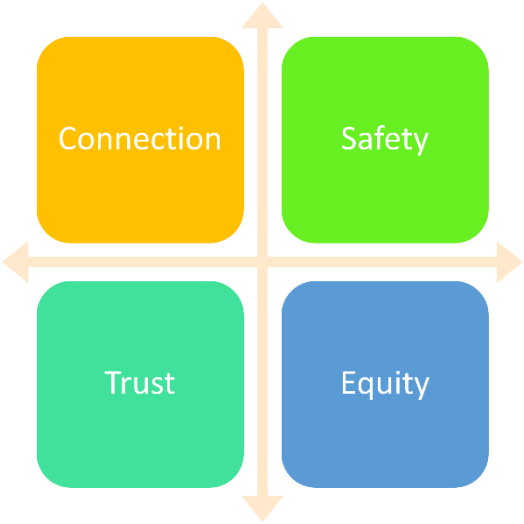
Patient engagement is the active engagement between regulators and patients, caregivers or patient advocates that enables patients to participate, consult, learn, and communicate bidirectional with regulators as part of the regulatory lifecycle of medical devices and drugs.

Key Principles

SFDA's patient engagement policy is based on key principles that ensure diversity, transparency and communication between patients and regulators. SFDA is committed to enhancing communication with patients to ensure the safety of public health with respect to the use of medical devices and drugs within Saudi Arabia. The following four principles guide all patient engagement activities provide a roadmap for regulators and patients who participate in these activities.

The four guiding principles for the SFDA's patient engagement policy are:

- **Connection**: Engaging with patients to gain access to real-life patient experience can enhance regulators' ability to effectively regulate medical products by supplementing clinical data with the real-life experience of patients.
- **Safety**: Enhancing the relationship between patients and regulators can improve patients' safe and rational use of medical products by understanding how patients manage their disease and treatments.



- **Trust:** Engagement with patients by regulators enhances trust, promotes integrity in the regulatory process, and improves transparency.
- **Equity:** Including the perspectives of diverse patient stakeholders ensures equity and the opportunity for SFDA to obtain a variety of patient perspectives.

Establishment of the Saudi Patient Engagement Program (SPEP)

The Saudi Patient Engagement Program (SPEP) is designed to serve all review branches of SFDA, including medical devices and drugs. The SPEP will be housed in the SFDA whose responsibility will be to implement, manage, and

maintain the SPEP under the oversight of the SFDA Commissioner or his designee. The SPEP will include several programs aimed at providing diverse opportunities for patients to engage with regulators. These programs will include the following:

1. Saudi Patient Network
2. Special Interest Working Groups
3. Community Patient Advisory Boards, and
4. Patient Engagement Portal

A Patient Advisory Council will be convened as needed at the discretion of the SFDA.

These programs will provide different avenues by which SFDA and patients engage and exchange information. Each program will have a process by which patient engagement activities occur, criteria for participation, and expectations for outcomes of the activity.

The SPEP will remain flexible in its ability to create new engagement opportunities should the need arise to address a specific therapeutic area or medical product need. Any program developed under the SPEP shall be based on the Key Principles and, whenever possible, developed with input from patients. SFDA may establish a training program for participants to enhance the quality of interaction between patients and regulators

Types of Patient Engagement

The SFDA Patient Engagement Program will include the following engagement opportunities in which patients and caregivers may participate.

- **Saudi Patient Network.**

  The Saudi Patient Network is a network of patient and caregiver "experts" who can provide input on patient experience or needs for a particular disease or treatment area. This network may include patient advocates, leaders in local hospital patient groups, or individuals with a knowledgeable interest in a particular disease area. Patients shall apply to participate and be identified as part of a "pool" of patients who might be invited to specific meetings with regulators, complete surveys on a particular topic, or participate in focus groups.

  Patients will apply via the Patient Engagement Portal and will be vetted by the SFDA. Criteria for participation in the Saudi Patient Network are established by the SFDA. At a minimum, patient experts must be willing to devote the needed time to participate in the activities for which the patient expert is recruited, understand the need for confidentiality, and be able to confidently share their experiences with regulators.

- **Special Interest Working Groups**

Patient and caregiver experts may participate as part of Working Groups with SFDA to address benefit/risk determinations for specific medical products, provide feedback on SFDA policies and programs, and engage with regulators to identify areas of unmet medical need in the KSA. Participation in a Working Group may require patients to have specific scientific knowledge. Criteria for participation in the Working Group will be determined by the SFDA. The criteria may vary depending on the topic of the Working Group. In general, patients should meet the minimum criteria for participation in the Saudi Patient Network, while being willing to commit to the additional time and effort that participation in the Working Group might entail. Patients who participate in the Working Groups may need to have specific expertise, knowledge, training, or experience to participate in a particular Working Group. The SFDA may desire to provide patients with additional training to enhance the ability of patients to contribute to a particular Working Group.

- **Community Advisory Boards**

Community Advisory Boards (CABs) can be used to create community-based patient and caregiver engagement by establishing local advocacy groups in regional hospitals or healthcare facilities. Community Advisory Boards may be used to provide organized feedback to SFDA about unmet medical needs in the local community, obtain input from patients on the design of clinical trials or research within the local patient community, and create a means by which SFDA collects early input about new medical products. Community Advisory Boards could also be a mechanism by which SFDA assesses the occurrence of adverse medical product experiences at the community level. Furthermore, Community Advisory Boards may provide a mechanism by which the patient community collaborates with academic, industry, and medical research leaders to address specific therapeutic area needs. Each Community Advisory Board should be led by a knowledgeable patient advocate appointed by the SFDA.

- **Patient Engagement Portal**

The SFDA will establish a web site that serves as a resource to the patient and caregiver community by providing details about patient engagement programs, means by which to participate in those programs, and delivery of results from patient engagement activities. The web site will also solicit input and feedback from the patient community by enabling patients to complete surveys on specific topics, provide general feedback to SFDA, and direct patients to participate in the Patient Experience data collection activities. Survey topics might include soliciting input about a specific therapeutic area, medical product, or regulatory issue. SFDA may also use the Patient Engagement Portal to obtain feedback on new policies or programs for which patient input is a critical component. The Patient Engagement Portal should facilitate two-way communication between the SFDA, patients and caregivers, and other stakeholders, thus enhancing engagement between SFDA and the community.

- **Patient Advisory Council**

  The patient advisory council may be a group of patients who are appointed to serve on a select council that meets to discuss a specific topic and provide SFDA with recommendations. This council would be made up of a diverse, but selected group of patients along with other experts or stakeholders needed to fully discuss the special topic at hand. These meetings would be open to the public for comment on a given topic. Criteria for participation in the Patient Advisory Council will be determined by the SFDA and will be based on patients' education, experience, or therapeutic area knowledge. The Patient Advisory Council is an optional component of the Patient Engagement Program. Use of the Patient Advisory Council is at the discretion of the SFDA.

Selection of Patients to SFDA Patient Engagement Program

SFDA will oversee recruitment of patients to the Patient Engagement Program while ensuring a commitment to diversity and attention to the program's Key Principles. The Patient Engagement Portal will be the main avenue by which the SFDA will recruit patient participants. Individuals interested in participating in one of the Patient Engagement Programs will use the Portal to learn about the types of engagement activities available to them, the criteria by which patients will be chose for participation, and how to apply to be part of the Patient Engagement Program activities.

The SFDA may use a broad range of criteria on which to select patients for various Patient Engagement Program activities. These criteria may include a broad diversity of: age, gender, disease or illness, education, region, and socio-economic status. If the SFDA is having difficulty engaging sufficiently diverse group of patients, they will endeavor to recruit patients to the Patient Engagement Program by various communication media. In addition, the SFDA may proactively seek out community patient leaders to establish Community Advisory Boards in a diversity of regions within the KSA.

Evaluation of the SFDA Patient Engagement Program

The SFDA will establish criteria by which the Patient Engagement Program is assessed for impact and effectiveness. Evaluation of the program activities should be based on a structured program evaluation technique using metrics for each of the following factors:

- Program objectives
- Expectations, preparations, resources, and representativeness of participants
- Activity structure, management, interactions, and satisfaction
- Learnings and changes based on the program activities
- Impact of the program including relevance, ethics and inclusiveness, quality and efficiency, patient empowerment, effect and timing on decision-making, and reputation of Patient Engagement Program

Patient Engagement Program activities should be evaluated on a yearly basis at a minimum. Specific initiatives, projects, Working Groups, research activities, or other focused efforts should be evaluated upon completion of the activity using metrics based on the factors listed above. Annual and specific program evaluations should be summarized and reported to SFDA leadership.

Saudi Patient Network

Mission

To provide a pool of patient and caregiver "experts", as well as patient advocates, who can provide regulators with input and understanding of living with a particular illness, accessing care, or experiences with treatment.

Objectives

To support or inform regulatory decision making, facilitate patient empowerment, maintain inclusiveness and diversity of patient input, achieve all engagement timelines, and expand, uphold and enhance reputation of SFDA in the greater community.

Resources required

The SFDA will reach out to patients, caregivers, and patient advocates who have applied, and been approved, to join the network. Patient Network participants should be provided onboarding materials to orient them to the program. For example, materials focused on training and education about the regulatory system should be available. Patients will also need to be provided with informational materials on confidentiality, as well as any background materials on relevant topics. The SFDA will need dedicated staff to generate the materials needed to education network participants. In addition, dedicated staff will be needed to plan and facilitate engagement with Saudi Patient Network participants. This may include development and distribution of surveys, scheduling phone interviews between participants and regulators, arranging patient attendance at meetings with regulators, or other activities to be determined by the needs of the SFDA.

Criteria for Participation:

Participation in the network will be determined by meeting several criteria based on the following definitions of potential network participants:

- **"Patients**" are defined as persons with personal experience of living with a disease, have undergone a specific type of treatment, or are caring for someone who meets these criteria. They may or may not have technical knowledge about medicine, medical therapies, or regulatory processes, but their main role is to contribute with their subjective experience with a particular disease, condition, or treatment area. Specifically, patients must have a diagnosed chronic condition, have undergone a specific treatment (e.g. orthopedic surgery), be undergoing treatment for a condition (e.g. cancer therapy), or be a caregiver of an individual who fits these criteria. Patients should be diverse in terms of gender, age, region, socio-economic status, and education.

- "**Caregivers**" may also provide patient representation and are defined as persons supporting individual patients. This can include family members, paid helpers, or

volunteer helpers. Patients and/or caregivers should also be able to communicate clearly in writing and verbally to participate in this program. This network may additionally include patient advocates.

- "**Patient Advocates**" are persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organization. This can include leaders in local hospital patient groups, or individuals with an interest in a particular disease area.

To participate in the network, individuals must fall into one of the defined categories of patient, caregiver, or advocate, and be willing to participate as needed in activities defined by the SFDA. At a minimum, network participants must be willing to devote the needed time to participate in the activities for which the patient expert is recruited, understand the need for confidentiality, and be able to confidently share their experiences with regulators

Recruitment of Participants

The SFDA will be responsible for recruiting participants to the Saudi Patient Network. Recruitment will ensure a diverse group of patients, caregivers, and advocates are brought into the network. Recruitment might occur by way of:

• Advertising opportunities for patient participation

• Open call for applicants on the Patient Engagement Portal

• Existing relationships with healthcare providers, hospitals, and researchers and other agencies

• Unsolicited requests previously made by interested parties

The Patient Engagement Portal will provide patients and caregivers with details about all the available patient engagement programs, as well as the option to apply to participate in any of the available programs. Patients will apply via the Patient Engagement Portal and will be vetted by the SFDA. Full criteria for participation in the Saudi Patient Network are established by the SFDA based on the activity to which the participants are being recruited.

Methods of Engagement

Engagement will include, but is not limited to, the following: participation in focus groups, completion of surveys, and provision of feedback regarding patient experience and patient needs. Participation would be on an as-needed basis when regulators have a particular desire to learn more about a specific therapeutic area.

- Types of input might include: patient experience with a specific medical device or drug treatment, the burden of living with a particular disease, unmet medical need in a particular therapeutic area, or patient's perceptions about access to therapy.

- Types of output from these activities might include: a report summarizing the subjective experience of participants, recommendations for regulatory policy or decisions about a new or existing therapy, changes to access or reimbursement for specific treatments, or requests for new regulatory science to be developed around novel devices or drugs.

Duration of Engagement

Participants must agree to participate in the network for one-year increments. For each year, the patient must apply to be part of the network. A patient may participate in the network for as many years as they like. There is no guarantee a patient will be needed by regulators in any given year. However, patients agree to participate in at least 2 – 3 phone calls, 1 – 2 surveys, and at least one focus group for any year in which they have applied and been accepted to participate in the network.

Evaluation of the Saudi Patient Network

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Has there been a meaningful impact on regulatory decision making
     - Have engagement deadlines and quotas been met for the year
     - Yearly feedback (including ratings, feedback, and suggestions) from SFDA sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from patient members collected through surveys and interviews
   - Evaluating Outcomes:
     - How well is the program meeting the objectives: patient empowerment, inclusiveness and diversity of patient experts, effect on decision making, reputation
     - Standards of operation:
       - Quality of program
       - Efficiency of program
       - Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes alongside long term vision

Special Interest Working Groups

Mission

To provide the patient perspective to Special Interest Working Groups lead by SFDA staff. Patient experts, along with patient advisors, healthcare providers, and other stakeholders as required may participate as part of Working Groups with SFDA to address benefit/risk determinations for specific medical products, provide feedback on SFDA policies and programs, and engage with regulators to identify areas of unmet medical need in the KSA. A Working Group might deliver a written recommendation, a report, a presentation, or other form of deliverable for consideration by SFDA leadership.

Objectives

To support or inform regulatory decision making, facilitate patient empowerment, maintain inclusiveness and diversity of patient input, achieve all engagement timelines, and expand, uphold, and enhance reputation of SFDA in the greater community.

Resources required

Patients who participate in the Working Groups may need to have specific expertise, knowledge, training, or experience to participate in a particular Working Group. In addition, the SFDA may desire to provide patients with additional training to enhance the ability of patients to contribute to a particular Working Group. Additionally, materials focused on training and educating about the regulatory system, the topic of the Working Group, and any other information the participants will need to successfully contribute will need to be developed and disseminated to all Working Group participants. Information about the purpose of the Working Group and the associated tasks will need to be developed to facilitate recruitment of participants to the Working Group. Meetings of the Special Interest Working Group will need to be planned and facilitated. Deliverables from the Special Interest Working Group (such as a written recommendation, a report, a presentation, or other form of deliverable for consideration by SFDA leadership) will need to be managed and delivered to SFDA leadership.

Criteria for Participation

Patients in a Special Interest Working Group may be required to meet more rigorous criteria for participation depending on the topic being addressed. These patients will function as “Patient Experts,” who, in addition to disease-specific expertise, have the technical knowledge in medical device and drug research and development and/or regulatory affairs through training or experience. The specific criteria for the patient experts may include a college education, specialized training in clinical research, engineering, or medicine, and/or have completed training provided by SFDA on policy development, regulatory affairs, or SFDA administrative practices. The team may additionally include regulators, patient advisors, healthcare providers, academic researchers, and other stakeholders as required. Each Special Interest Working Group will need to

be defined by the SFDA with specific criteria for recruitment to ensure all stakeholders can contribute equitably to the assigned task.

Recruitment of Participants

The Patient Engagement Portal will provide potential working group participants with details about all of the available patient engagement programs, as well as the option to apply to participate in any of the available programs. Specific information about a given Working Group task will be disseminated as needed to recruit participants. Patients who participate in a Special Interest Working Group may be identified from the Saudi Patient Network or may be recruited by the SFDA to serve specifically on a Working Group. The SFDA may proactively solicit participation of healthcare providers and academic researchers and other stakeholders if needed for a particular working group. Recruitment might occur by way of:

- Advertising opportunities for patient participation
- Open call for applicants on the Patient Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

Participation would be on an ongoing basis for a specified period of time. The SFDA may desire to provide patients with additional training to enhance the ability of patients to contribute to a particular Working Group. The team, consisting of patient experts, regulators, patient advisors, healthcare providers, and other stakeholders will meet several times throughout the year, and will create deliverables consisting of a written recommendation, a report, a presentation, or other form of deliverable for consideration by SFDA leadership.

Duration of Engagement

The work to be completed by a Special Interest Working Group should be achievable in 6 – 12 months. Patient advisors on a working group should not be required to serve for more than 12 months. The working group should meet no more than 1 – 2 times per month. Virtual participation should be available. Participation in a working group should not interfere with the patient's work or home life commitments.

Evaluation of Special Interest Working Groups

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.
2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Has there been a meaningful impact on regulatory decision making
     - Have engagement deadlines and quotas been met for the year
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from patient advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews
   - Evaluating Outcomes:
     - How well is the program meeting the objectives: patient empowerment, inclusiveness and diversity of patient experts, effect on decision making, reputation
   - Standards of operation:
     - Quality of program
     - Efficiency of program
     - Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes alongside long term vision

Community Advisory Boards (CABs)

Mission

To create local advocacy groups in regional hospitals or healthcare facilities to provide an avenue for interaction and exchange between the local patient community and academic, industry, and medical research leaders as well as to provide organized feedback to SFDA about addressing unmet medical needs in the local community, obtain input from patients on the design of clinical trials or research within the local patient community, and create a means by which SFDA collects early input about new medical product, adverse events, treatment access, and patient experience.

Objectives

To support or inform medical research and regulatory decision making, facilitate patient empowerment, maintain inclusiveness and diversity of patient input, achieve all engagement timelines, and expand, uphold, and enhance reputation of SFDA in the greater community.

Resources and planning

It is important to have a facilitator or patient advocate appointed by the SFDA who can organize the community meetings, and act as a liaison between CAB members, academic, industry, and medical research leaders, and the SFDA. This facilitator will also be responsible for providing administrative tasks such as generating materials before the meetings, note taking during meetings, and sending notes and follow up actions after meetings to CAB members and SFDA. The CAB facilitators should be assigned in all regional areas in which CAB activities will take place. The location of the CAB facilitators might be at a local hospital or other regional healthcare facility where CAB activities might take place.

CAB facilitators may be paid or unpaid depending on the availability of resources, and the amount of work expected from the facilitator. Furthermore, the venue and travel/accommodation costs for patients and academic, industry, and medical research leaders may be paid or unpaid. If involved, funding needs to be transparent. For example, SFDA may set up a website that details costs associated with supporting CAB activities. Cost transparency should follow applicable laws and regulations for transparency.

CAB members may receive training in order to join. Materials focused on training and educating about the regulatory system should be available on the Patient Engagement Portal. CAB Members will also need to be provided with informational materials about confidentiality and conflict of interest as it applies under local laws and regulations. If a CAB meeting is sponsored by the medical device or pharmaceutical industry, confidentiality agreements and declaration of interest agreements may be required of CAB members in order to participate.

Criteria for Participation

A facilitator who organizes CAB meetings and is responsible for the activities described above may be a health professional or health expert, such as a doctor or nurse. This person will act as a liaison between the CAB member patient community, academic, industry, and medical research leaders, and the SFDA. Patient representatives must be patients who have a diagnosed chronic condition, have undergone a specific treatment (e.g. orthopedic surgery), be undergoing treatment for a condition (e.g. cancer therapy), or be a caregiver of an individual who fits these criteria. Patients should be diverse in terms of gender, age, region, socio-economic status, and education.

Patients and/or caregivers should also be able to communicate clearly in writing and verbally to participate in this program, and be willing to undergo training related to their participation in the CAB. Academic researchers, healthcare providers, and industry representatives who participate in a CAB must have relevant clinical experience with the therapy or disease being discussed. A CAB should be open and transparent about the criteria and processes for members, as well as the meeting participation for and academic, industry, and medical research leaders. There should be a good balance between the number of academic, industry, and medical research leader representatives who should attend each meeting and CAB member representatives.

Recruitment of Participants

The Patient Engagement Portal will provide potential CAB participants with details about all of the available patient engagement programs, as well as the option to apply to participate in any of the available programs. Specific information about CABs will be disseminated as needed to recruit participants. Patients who participate in a CAB may be identified from the Saudi Patient Network or may be recruited by the SFDA to serve specifically on a CAB. The SFDA may proactively solicit participation of healthcare providers and academic researchers and other stakeholders if needed for a particular CAB. Recruitment might occur by way of:

- Advertising opportunities for patient participation
- Open call for applicants on the Patient Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

CAB facilitators may be SFDA staff, or may be recruited by way of the Patient Engagement Portal, special invitation, or by SFDA based on their current role in the local patient community (e.g., an advocate or community leader).

Methods of Engagement

Meetings of the CAB may take place regularly throughout the year, at least once per year. Meetings may be a half day or a full day long. Meetings may take place at regional hospitals or healthcare facilities. While CAB meetings should typically be in person, virtual meetings may also be utilized. The CAB facilitator will send topic preparation materials before the meetings and send meetings notes and follow up actions after meetings to CAB members. Typically, information shared with members and attendees is considered confidential. Any information and materials provided to members should avoid any promotional, commercial, or marketing messages or any bias toward any specific brand. The facilitator is responsible for initiating the contact with academic, industry, and medical research leaders and CAB members, determining what topics are important to the patient community, and choosing the topic of discussion for each meeting.

Topics may also be chosen by the SFDA or other SFDA leadership. Topics may range from general research within a particular disease area (including research pipelines or access to treatment), to specific suggestions for clinical trials (materials for trial participants), or treatment access (pricing and quality control). CAB Members may additionally meet without the academic, industry, and medical research leaders before and after each meeting. If meeting with a company, there may need to be a confidentiality agreement and declaration of interest agreements CAB members need to sign with the participating company.

Duration of Engagement

Meetings may last a half day to a full day. A time commitment for membership of 2 years is suggested.

Evaluation of Community Advisory Boards (CABs)

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - CAB may follow progress with a Tracke
     - Is there regular meaningful interaction between CAB members, academic, industry, and medical research leaders, and the SFDA
     - Does the exchange of information have an effect on medical research or industry
     - Has any regulatory decision making has been affected by this program
     - Is there a meeting quota for the year

- Are meeting attendees (including patients and academic, industry, and medical research leaders) receiving planning materials and follow-up notes.
- After each CAB meeting an online survey is sent to CAB members and any academic, industry, and medical research leaders involved in the meeting to assess success and satisfaction
- Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
- Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
- Yearly feedback (including ratings, feedback and suggestions) from academic, industry, and medical research collaborators collected through surveys and interviews

- Evaluating Outcomes
  - How well is the program meeting the objectives
  - Standards of operation:
    - Quality of program
    - Efficiency of program
    - Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes

Patient Engagement Portal

Mission

To establish a web site that serves as a resource to the patient and caregiver community by providing details about patient engagement programs, means by which to participate in those programs, and delivery of results from patient engagement activities. The web site will also solicit input and feedback from the patient community.

Objectives

To support or inform regulatory decision making, facilitate patient empowerment, maintain inclusiveness and diversity of patient input, achieve all engagement timelines and expand, uphold and enhance reputation of SFDA in the greater community.

Resources required

The planning and development of the Patient Engagement Portal will be required. Designated resources will be need for copywriting and content development related to details about patient engagement programs, means by which to participate in those programs, and delivery of results from patient engagement activities. Surveys on specific topics, Patient Experience data collection activities. Survey topics might include soliciting input about a specific therapeutic area, medical product, or regulatory issue. Materials focused on training and educating about the regulatory system should be available. Obtaining feedback on new policies or programs will require regular website maintenance and a review of surveys and feedback. Additional resources may be needed to analyze survey data, generate reports from patient engagement activities conducted by way of the Patient Engagement Portal, and to provide updated information to patients, caregivers, and other stakeholders.

Criteria for Participation

The Patient Engagement Portal should be easily accessible and freely available to the public in the KSA.

Recruitment of Participants

The Patient Engagement Portal will provide potential patient engagement participants with details about all of the available patient engagement programs, as well as the option to apply to participate in any of the available programs. Recruitment of participants into the many possible patient engagement programs might occur by way of:

- Advertising opportunities for patient participation
- Open call for applicants on the Patient Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

Patients and caregivers may interact with the Patient Engagement Portal whenever they like. The web site should be easily accessible to the public and designed to enhance engagement with all patients, including those with special needs (e.g. larger font for vision impaired). The Patient Engagement Portal should facilitate two-way communication between the SFDA, patients and caregivers, and other stakeholders. The portal will provide patients and caregivers with details about all of the available patient engagement programs, as well as the option to apply to participate in any of the available programs. The portal will also provide the results of patient engagement activities, and link to the Patient Experience Program. Patients will be able to use the portal to provide feedback and input in several ways. The web site will enable patients to complete surveys on specific topics and provide general feedback to SFDA.

Survey topics might include soliciting input about a specific therapeutic area, medical product, or regulatory issue. Patients will also be directed to participate in the Patient Experience data collection activities. SFDA may additionally use the Patient Engagement Portal to obtain feedback on new policies or programs for which patient input is a critical component.

Duration of Engagement

The Patient Engagement Portal will be an ongoing effort by SFDA to engage with the patients, caregivers, and other stakeholders. The website will be maintained and updated regularly by the SFDA.

Evaluation of Patient Engagement Portal

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Is there regular meaningful interaction between patient members and the SFDA
     - Does the exchange of information have an effect on regulatory decision making
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from academic, industry, and medical research collaborators collected through surveys and interviews

   - Evaluating Outcomes:
     a. How well is the program meeting the objectives
     b. Standards of operation:
        i. Quality of program
        ii. Efficiency of program
        iii. Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes alongside long term vision

Patient Advisory Council

Mission

The Patient Advisory Council is a means by which the SFDA can bring together an *ad hoc* group of patients, caregivers, and other experts or stakeholders in a public setting to discuss and provide recommendations to the SFDA. The use of a Patient Advisory Council is at the discretion of the SFDA.

Objectives

To support or inform regulatory decisions making, facilitate patient empowerment, maintain inclusiveness and diversity of patient input, achieve all engagement timelines, and expand, uphold, and enhance reputation of SFDA in the greater community.

Resources required

A Patient Advisory Council meeting would need to be moderated by SFDA personnel. In addition, materials related to the topic would need to be generated and disseminated to the council participants. Further, organization of those who wish to provide public comment on the topic of interest will need to occur prior to the meeting. The council meeting and applications for participation on the council and to present public comment should be available on the Saudi Patient Portal. Resources for taking notes, recordings, and generation of summary reports following the council meeting will also be required.

Criteria for Participation

Patients in a Special Interest Working Group may be required to meet more rigorous criteria for participation depending on the topic being addressed. These patients will function as “Patient Experts,” who, in addition to disease-specific expertise, have the technical knowledge in medical device and drug research and development and/or regulatory affairs through training or experience. The specific criteria for the patient experts may include a college education, specialized training in clinical research, engineering, or medicine, and/or have completed training provided by SFDA on policy development, regulatory affairs, or SFDA administrative practices. The team may additionally include healthcare providers, academic researchers, and other stakeholders as required.

Those who wish to deliver public comment at the council meeting must apply by means of the Saudi Patient Portal. Criteria for delivery of public comment is at the discretion of the SFDA. However, at a minimum, public commenters should be required to provide the topic they wish to discuss, and abstract of their comments, and any slides they intend to present in advance of the meeting.

Recruitment of Participants

The Patient Engagement Portal will provide potential advisory council participants with details about all of the available patient engagement programs, as well as the option to apply to participate in any of the available programs. Specific information about a given Patient Advisory Council assembly will be disseminated as needed to recruit participants.

Patients who participate as part of a Patient Advisory Council may be identified from the Saudi Patient Network or may be recruited by the SFDA to serve specifically on a particular council. The SFDA may proactively solicit participation of healthcare providers and academic researchers and other stakeholders if needed for a particular advisory council activity. Recruitment might occur by way of:

- Advertising opportunities for patient participation
- Open call for applicants on the Patient Engagement Portal
- Existing relationships with healthcare providers, hospitals, and researchers and other agencies
- Unsolicited requests previously made by interested parties

Methods of Engagement

Participation would be for the duration of one Patient Advisory Council meeting and the time need to prepare for the meeting. The SFDA may desire to provide patients with additional training to enhance the ability of patients to contribute to the council's objective. The council participants, including patients, healthcare providers, and others chosen to be on the council should meet at least once prior to the advisory council meeting to ensure alignment on the agenda and objectives. The advisory council participants may be asked to review the summary report to ensure all recommendations are accurately captured and communicated in the report.

Duration of Engagement

Participation as part of a Patient Advisory Council should be limited to the time to prepare for the council meeting, attendance at the meeting, and review of the summary report following the meeting. The Patient Advisory Council and public comment should be scheduled to occur over the course of one full day. Should the topic require additional time, the council and public comment could occur over two full days. Topics that require more commitment than this should be addressed by a Working Group instead. Patient participation in preparation for the Patient Advisory Council meeting should be for no more than two months prior to the meeting and include one gathering of the entire advisory council to ensure alignment on the agenda and objectives.

Evaluation of Patient Advisory Council

1. **Expected Outcomes:**
   - Fulfill stated objectives
   - Upholding high standards of operation including efficiency, quality, and ethics.

2. **Monitoring and Evaluating Outcomes:**
   - Monitoring outcomes:
     - Has there been a meaningful impact on regulatory decision making
     - Have engagement deadlines and quotas been met for the year
     - Yearly feedback (including ratings, feedback and suggestions) from Regulatory Body (SFDA) sources collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from Patient members collected through surveys and interviews
     - Yearly feedback (including ratings, feedback and suggestions) from patient advisors, healthcare providers, and other stakeholders if applicable collected through surveys and interviews
   - Evaluating Outcomes:
     - How well is the program meeting the objectives: patient empowerment, inclusiveness and diversity of patient experts, effect on decision making, reputation
   - Standards of operation:
     - Quality of program
     - Efficiency of program
     - Ethics review

3. **Learnings and Changes:**
   - Assessment of gaps
   - Steps to improve
   - Continual assessment of the relevance of outcomes alongside long term vision

Rules for Engagement with Patients and Caregivers

The following are guidelines for engagement of SFDA with patients, caregivers, and advocates within all of the patient engagement programs described in this policy. These "rules for engagement" are based on the values of the patient engagement program to promote connection, safety, trust, and equity between SFDA and the public. These rules of engagement may be expanded or modified as the patient engagement programs and patient advocacy in the KSA evolve.

1. **Identify the Issue**: prior to initiating a patient engagement activity, the issue to be addressed by the activity must be identified, clearly defined, and documented. Clear identification of the issue will allow for a determination of which patient engagement activity is best suited to address the issue, what the objectives of the activity should be, and what the desired outcome from the activity is.

2. **Communicate Clear Objectives:** the objectives and desired output of patient engagement activities should be clearly defined and communicated to all stakeholders involved in the activity.

3. **Establish Structure:** the structure of the patient engagement activity should be clearly defined and communicated to all stakeholders. This structure should include roles and responsibilities for each participant and clearly defined accountability for the activities being undertaken by the participants.

4. **Create Space for Expression:** the mission of the patient engagement program is to encourage input from patients, caregivers, and patient advocates. As such, participants in patient engagement activities should feel empowered to speak their experience, express their views, and provide their perspective in a respectful, open, safe, and positive environment.

5. **Define Expectations:** each participant should have a clear understanding of the amount of time they will be expected to participate in the activity, what their role is, how they will be asked to communicate, what the type of work is they will be expected to complete, and what the activity should accomplish when it is complete. These expectations should also include details of any required travel, training, or other requirements expected of the participants. Expectations should be provided in writing to participants, who may be asked to sign and agreement indicating they understand the activity in which they will be engaged.

6. **Address Conflict Resolution**: each patient engagement activity should have a means by which conflict is addressed and resolved. Conflict resolution should be based on acceptable codes of conduct for the organizations involved. For example, the standards for conflict resolution at SFDA may be the model applied to patient engagement activities if appropriate. Alternatively, if a research organization is leading a patient engagement activity, the research organization's standards for conflict resolution may take precedence.

7. **Implement Standards for Compensation:** each of the patient engagement activities should have associated compensation standards applied to it based on local laws, regulations, or other applicable requirements. Patients, caregivers, advocates, and other patient engagement stakeholders should be aware whether or not they will be compensated for their time and expenses. Compensation policy should be made available for consideration by anyone being asked to participate in a patient engagement activity prior to them making a commitment to do so.

8. **Maintain Confidentiality:** each patient engagement activity will have a level of confidentiality associated with the activity and the outputs. Participants should be made aware of the requirements for confidentiality and may be asked to sign confidentiality agreements depending on the nature of the content or level of confidentiality required. All participants should adhere to confidentiality requirements of any patient engagement activity in which they participate. Confidentiality should not be used unnecessarily to impede transparency of the patient engagement program.

9. **Provide Support:** participants in the patient engagement program should be provided with support for logistical issues, questions regarding the programs, their participation, or compensation, help with travel arrangements and accommodations, or other needs. This support should be easy to find and contact information for the support team should be provided to all participants involved in the patient engagement program.

10. **Evaluate and communicate:** the patient engagement program activities should be evaluated annually, and a report should be generated and made publicly available. This report should highlight the success and achievements of the program activities. The report should also identify areas for improvement, lessons learned, and proposals for change. Further, the report should summarize recommendations from patients, caregivers, and patient advocates collected as part of the program evaluation portion of each patient engagement program. Finally, those who participate in one of the patient engagement programs should have access to information about how their participation had an impact. This may be included in the annual assessment report, or in reporting following individual patient engagement activities (e.g. a Working Group summary report).