الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Guidance on Registration and Reporting through Saudi National Vigilance System "Tayaquth" for Health Care Providers

National Pharmacovigilance Center

Data Capture Section

The main objective of National Pharmacovigilance Center is to maintain the safety and efficacy of medications and vaccines. And to achieve this objective the NPC encourages all health care providers to contribute in reporting of adverse drug events weather expected or unexpected, serious or non-serious as soon as possible.

Reporting ADE is a cornerstone in monitoring of all marketed medications and vaccines, and ensuring their safety.

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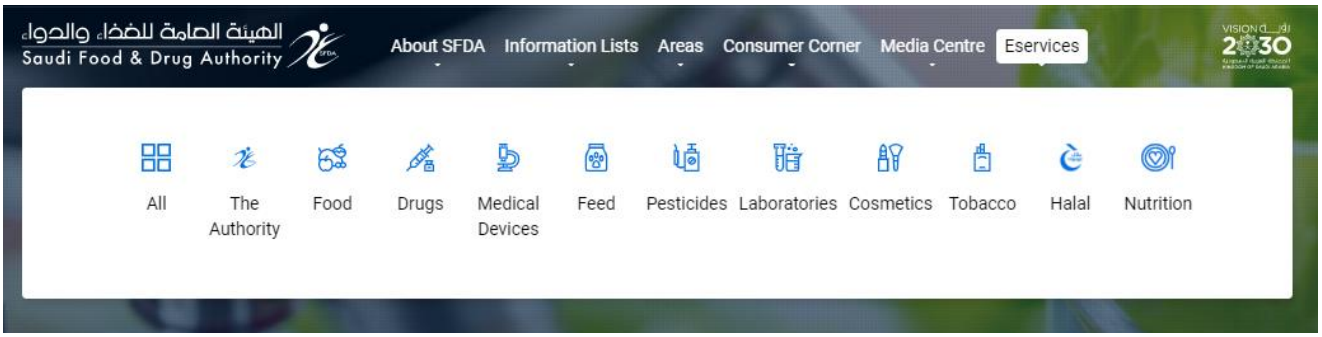
A. Registration

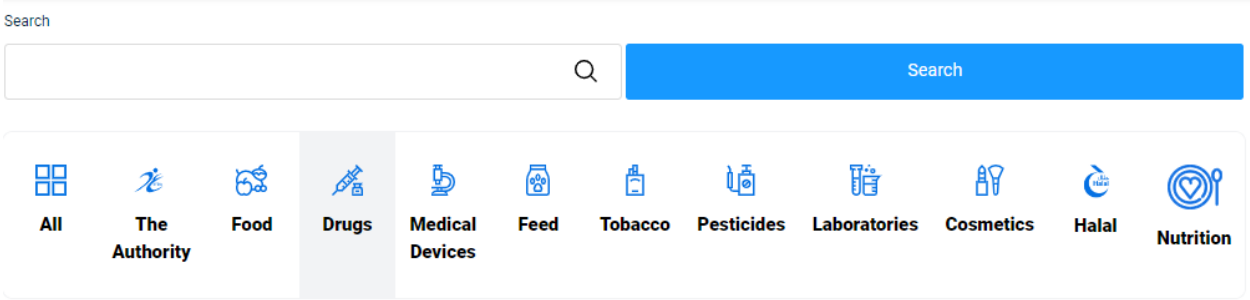
How to register on Saudi National Vigilance System "Tayaquth"?

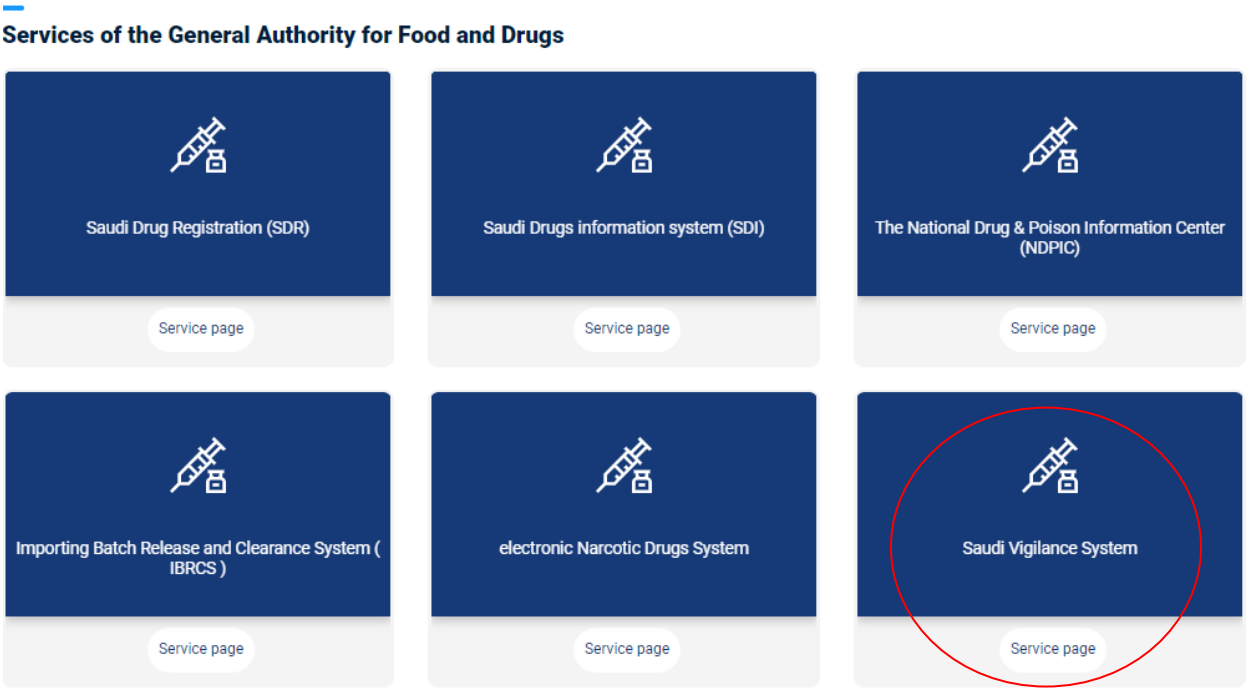
Registration will save time and efforts and make it easier for data entry, since the system will retrieve the registered information and no need to re-enter them by the reporter.

Where can you find the service link?

1. Direct link: https://ade.sfda.gov.sa/
2. Or through Saudi FDA website : https://www.sfda.gov.sa/en
3. Go to "**E-services**" from the top panel
4. Click on "**Drug**" from the drop list
5. Choose "**Saudi Vigilance System**"



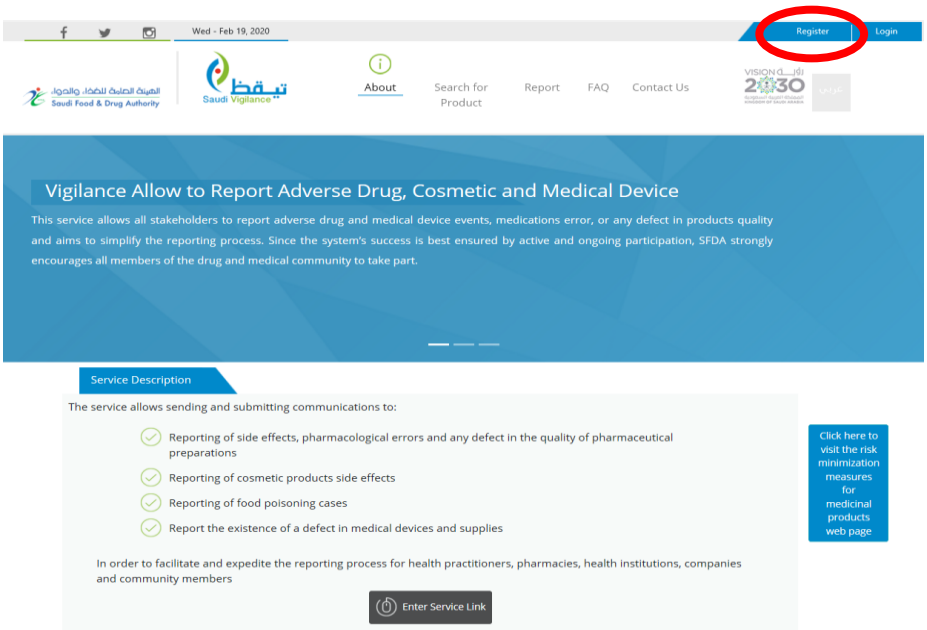




Now, you can start registration process

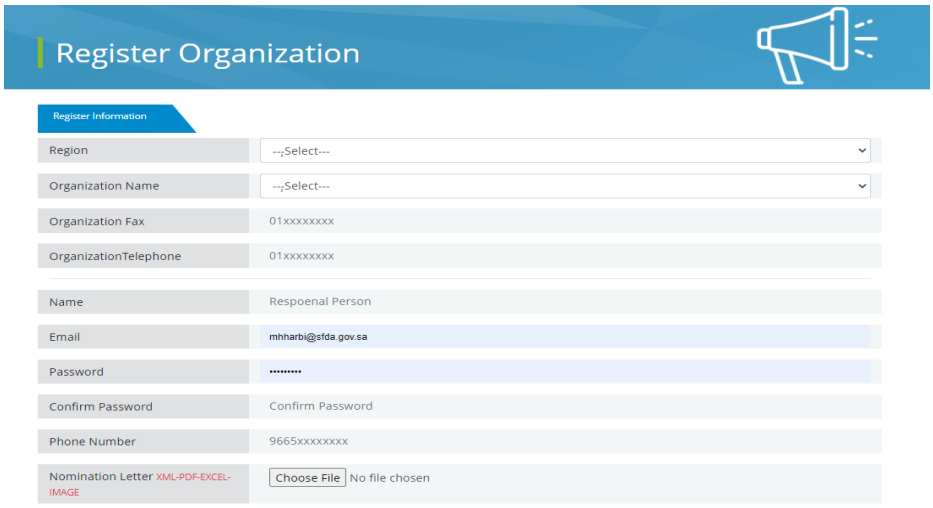
Registration of Health Organization

a. Go to "**Registration**" from the top panel



b. Click on "**Register Organization**"

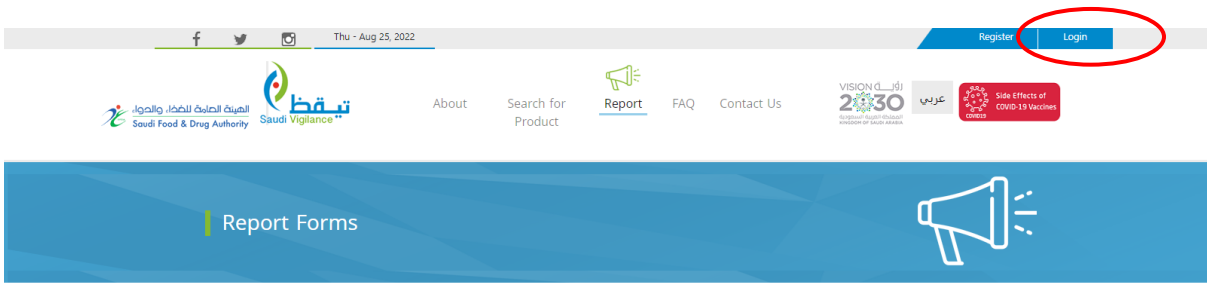
c. Complete registration information, then attach *Nomination letter and click "**Save**"



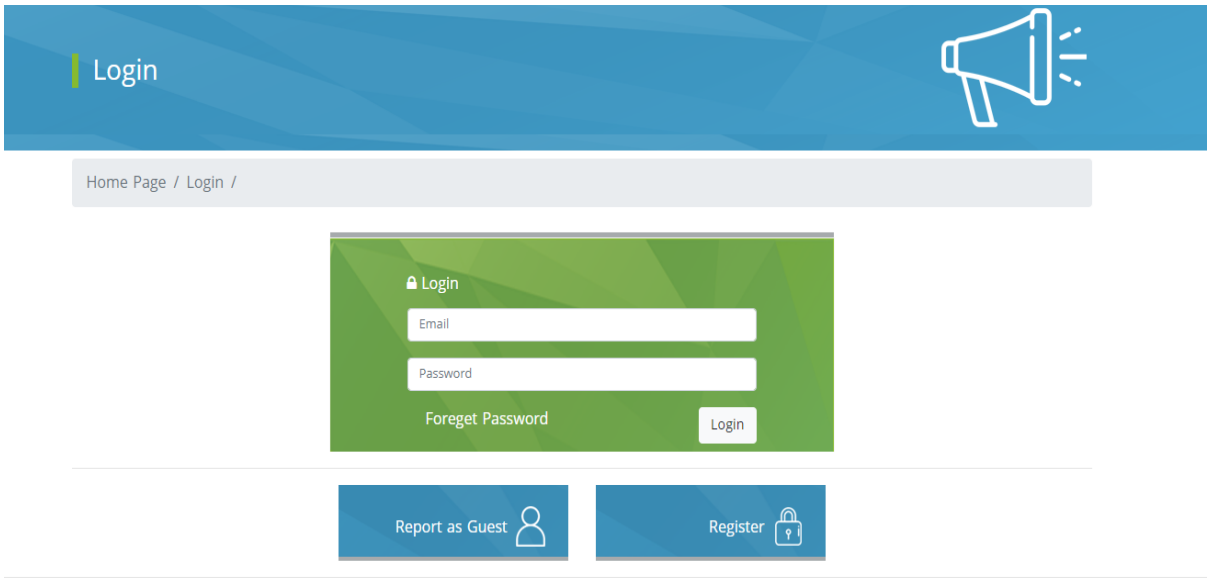
*Note: the nomination letter will allow the person who is responsible for the organization to delegate a main user responsible for the reporting on the system. It doesn't require a specific format, only the name for the main user, signature of the delegator and stamp of the organization

B. Reporting

1. Log in to your registered account

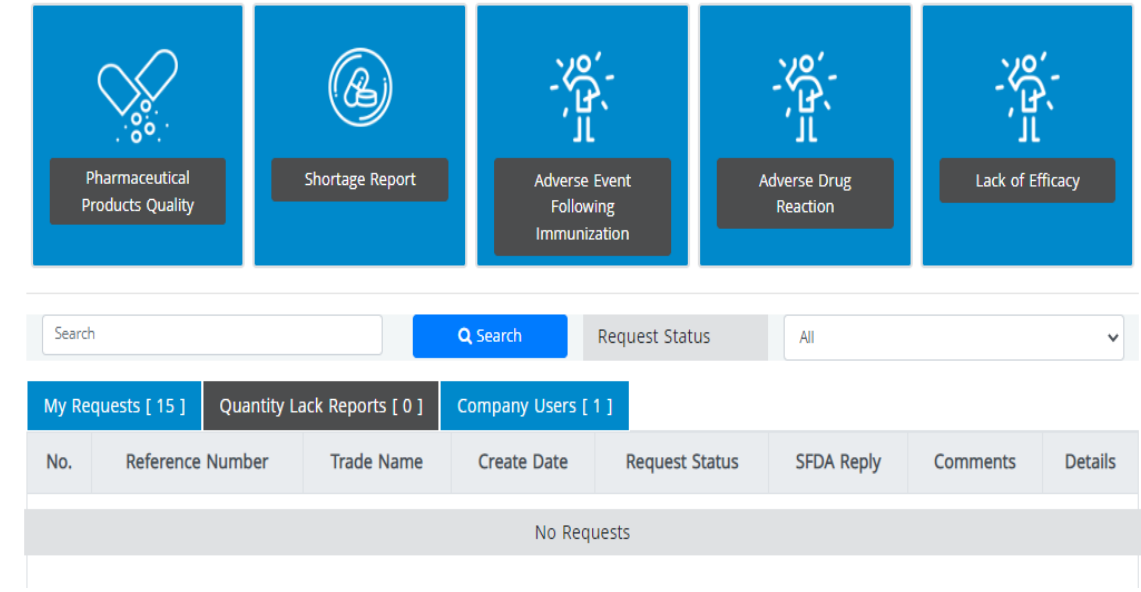


2. Enter your Email and password



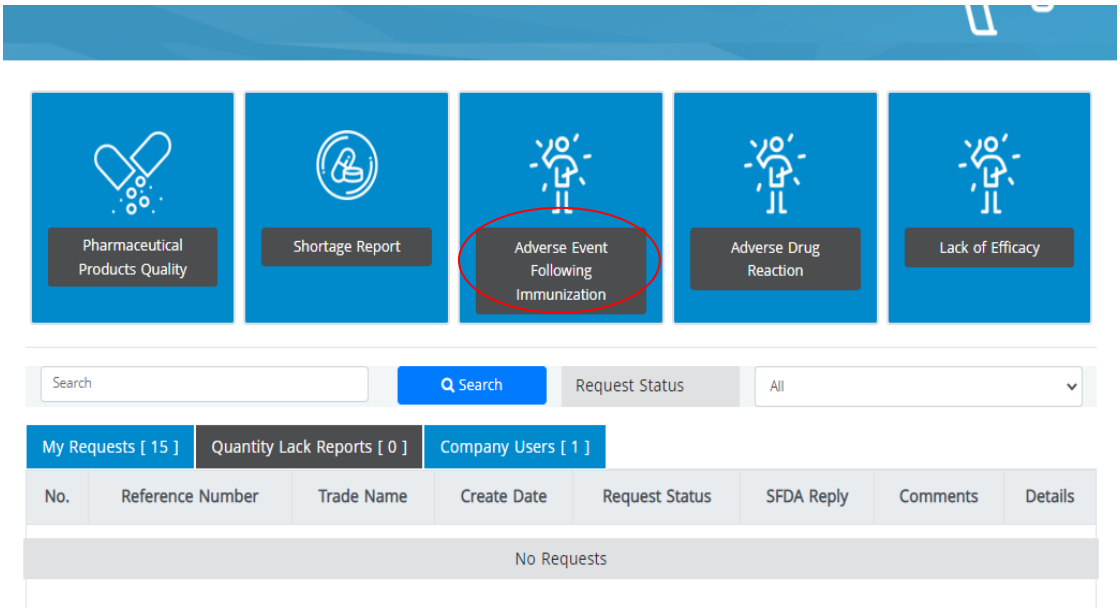
3. It will shows the reporting forms according to the type of report

I. "Pharmaceutical product quality" form: reporting on product quality issues
II. "Shortage report" form: reporting unavailable products and their alternatives
III. "Adverse events following immunization" form: reporting adverse events after receiving vaccines
IV. "Adverse drug reactions" form: reporting adverse reactions after drug administration
V. "Lack of efficacy" form: reporting the lack of expected response following product administration

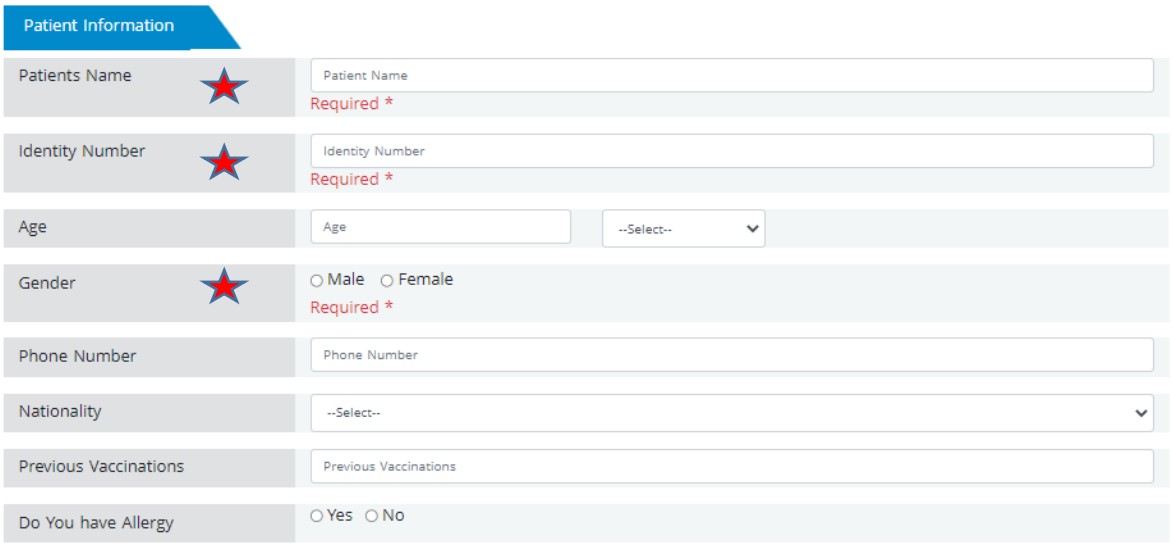


Reporting "Adverse events following immunization" through Saudi Vigilance System

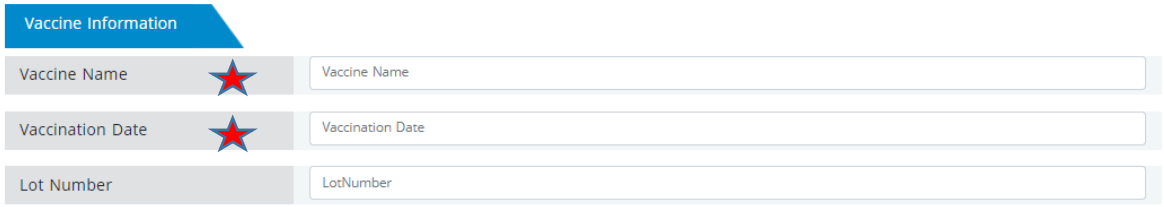
1. Click on "**Adverse events following immunization**" form



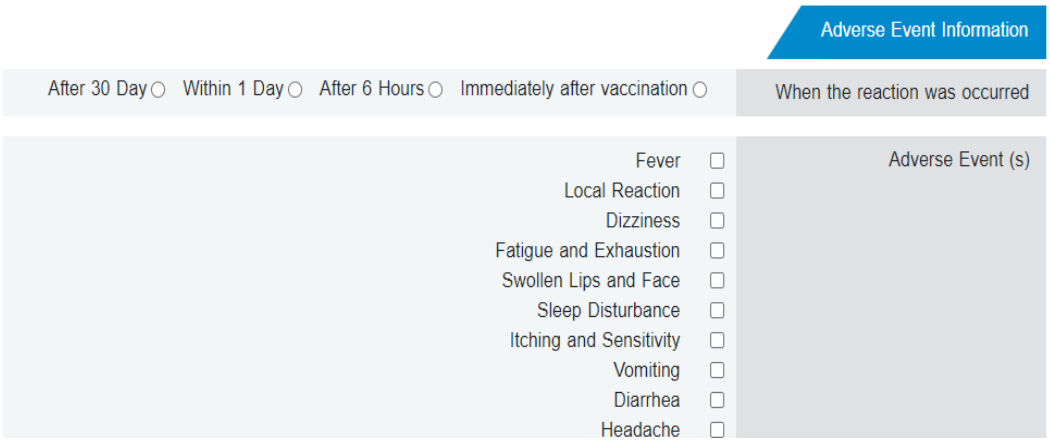
2. Fill out the Patient Information

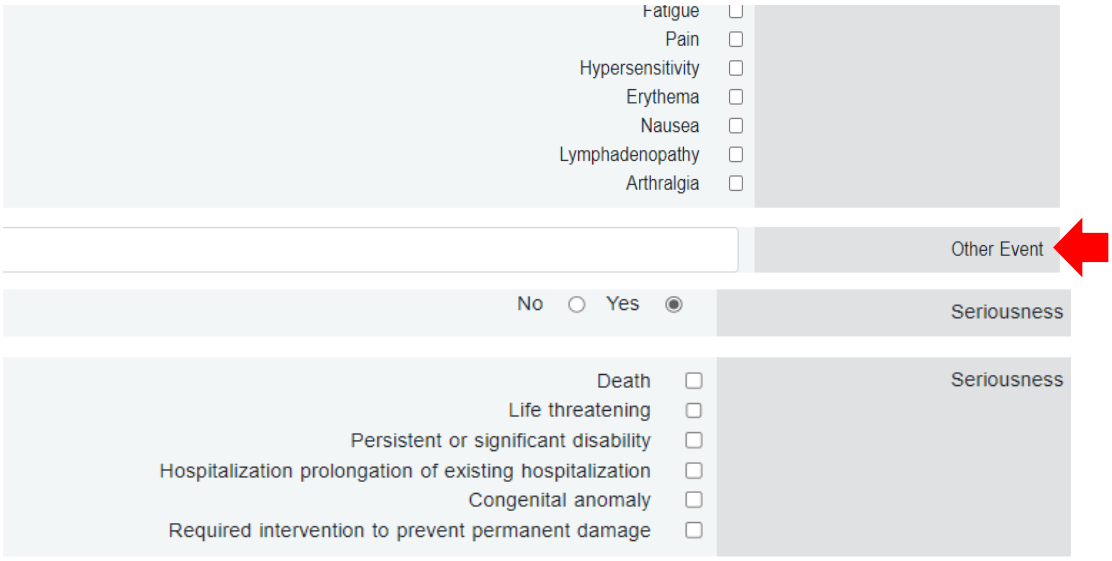


3. Enter the Vaccine Information



4. Complete the Adverse Event Information by choosing from the list or write it down in "Other event" field, in case it wasn't mentioned in the list. After that, specify the seriousness of the event (serious or non-serious) according to the seriousness criteria.

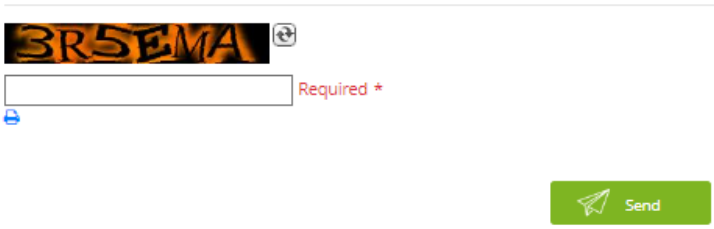




5. Case Investigation: choose "yes" incase investigation needed in order to build investigation reports and follow-up with the case, and this depends on the seriousness of the event

Note: choosing "yes" will forward the case automatically to the colleagues in the National Immunization Program

6. Make sure you have completed all the required fields, enter the code then click "send"

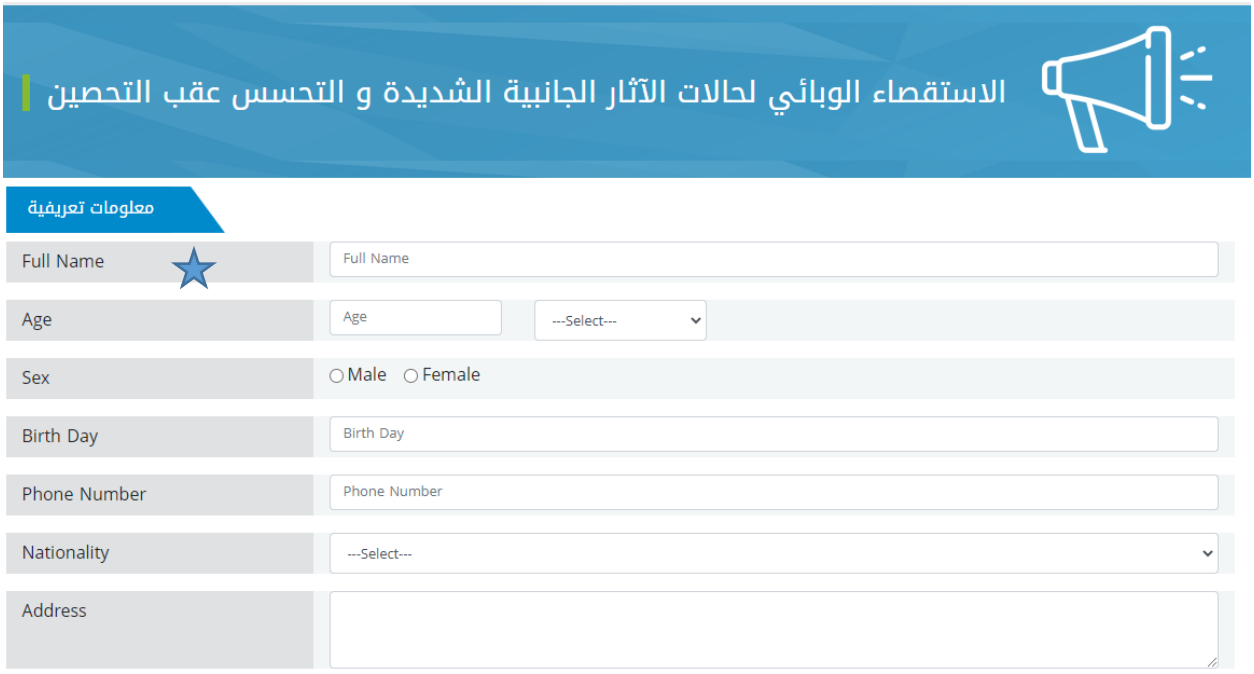


C. Investigation

Upon completion of Adverse events following immunization form, and choosing the option "Investigation needed", the investigation report will appear to be filled out by the reporter

How to build an Investigational Report?

1) Enter patient information with full name



2) Enter vaccine information, and patient's current health status (don't forget to specify the dates)

اللقاح

أعطي في	○ التطعيم الروتيني ○ حملة تطعيمية ○ أخرى Please Specify
تاريخ/وقت التطعيم	تاريخ/وقت التطعيم

أسماء اللقاحات والأمصال وكمية الجرعة التي أعطيت للمريض في هذا اليوم

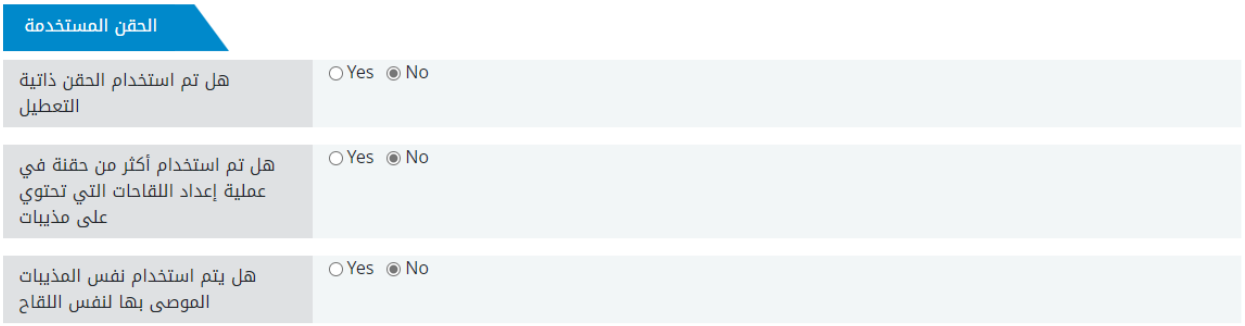
اسم اللقاح	
الجرعة	--Select--
طريقة الإعطاء	
الشركة المصنعة	
Batch Number	
Expiry Date	
	+
تاريخ انتهاء صلاحية اللقاح	1/1/0001 12:00:00 AM

مصدر المعلومات لما ورد في البندين	مصدر المعلومات لما ورد في البندين
من أين ومتى أرسل اللقاح لوحدة التحصين	من أين ومتى أرسل اللقاح لوحدة التحصين
نتائج الفحص المخبري للقاح (في حالة الاشتباه في تغير اللقاح)	نتائج الفحص المخبري للقاح (في حالة الاشتباه في تغير اللقاح)
اسم من قام بإعطاء اللقاح	اسم من قام بإعطاء اللقاح
اسم من قام بإجراء الكشف قبل التطعيم	اسم من قام بإجراء الكشف قبل التطعيم
الوضع الصحي الحالي للمريض	○ Recovered ○ Recovering ○ No Improvement ○ Fatal
Death Date	1/1/0001 12:00:00 AM

ملاحظات عن أسلوب حفظ وتداول اللقاحات الأخرى الموجودة بالموقع

درجة حرارة حفظ اللقاح	درجة حرارة حفظ اللقاح
المذيبات	المذيبات
الحقن	الحقن
نوع صندوق حمل اللقاحات و طريقة حفظ اللقاح	نوع صندوق حمل اللقاحات و طريقة حفظ اللقاح

3) Specify the type of vaccine and route of administration



4) Describe the details of the event (onset dates, Laboratory results, treatment..)

5) Choose the event’s outcome and category, then enter the code and send

نتيجة الأثر الجانبي

نتيجة الأثر الجانبي	☐ الآثار الجانبية شكلت خطورة على حياة المريض ☐ استدعيت حجز المريض بالمركز الصحي ☐ استدعيت حجز المريض بالمستشفى ☐ أدت إلى إعاقة دائمة
تصنيف الأثر الجانبي للقاح	☐ خراج بكتيري ☐ خراج عقم ☐ التهاب موضعي شديد ☐ تفاعل موضعي ☐ آثار على الجهاز العصبي ☐ شلل فجائي ☐ شلل أطفال له علاقة باللقاح ☐ متلازمة جليان باري ☐ اعتلال الدماغ ☐ التهاب الدماغ ☐ التهاب أغشية المخ ☐ نوبات تشنجية مع ارتفاع درجة الحرارة ☐ نوبات تشنجية دون ارتفاع درجة الحرارة ☐ فقد السمع
اسم الطبيب	Name of Physician/Doctor Who receive the case