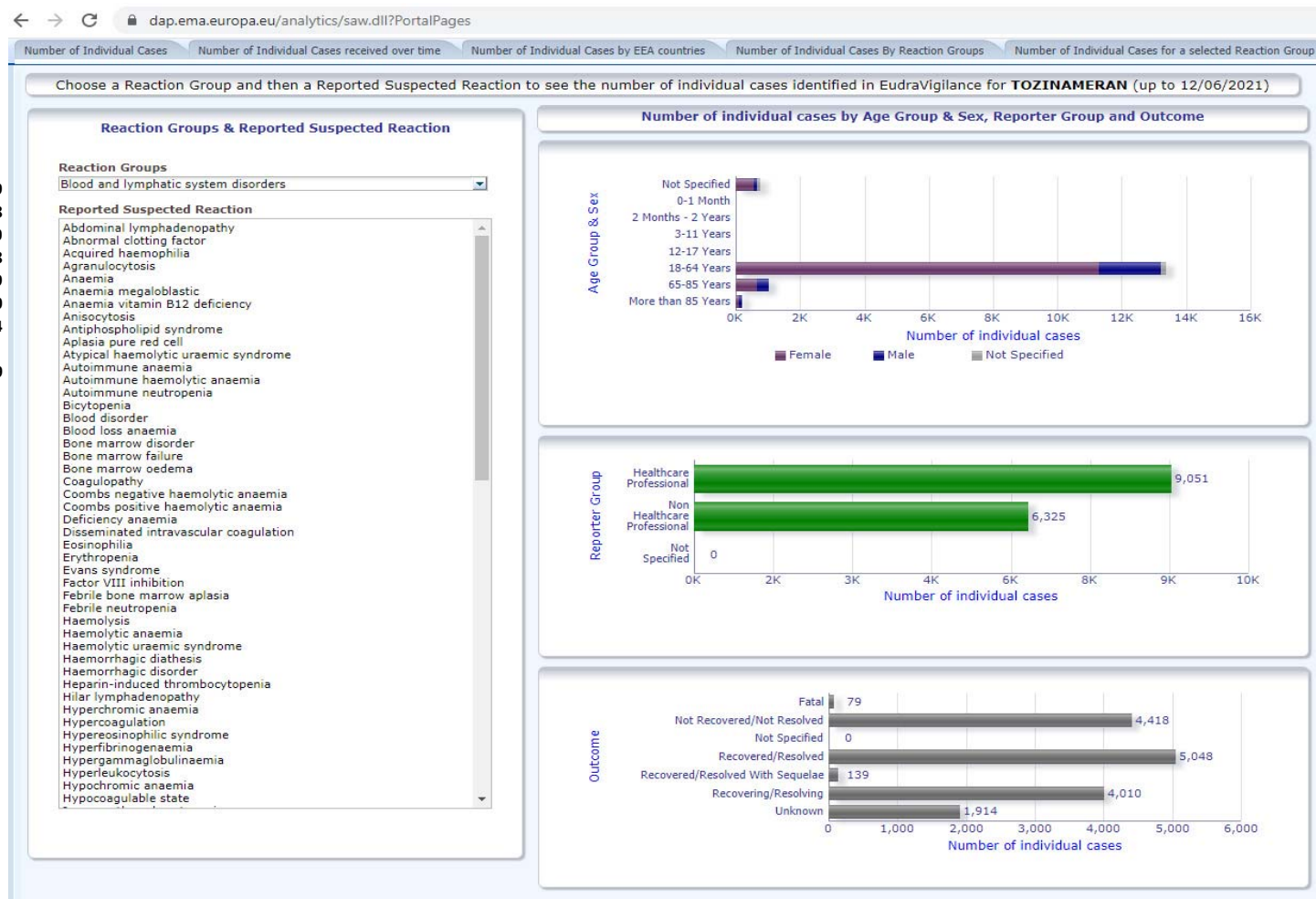


Reaction group 1:  
Blood and lymphatic system disorders

Fatal: 79  
Not recovered: 4418  
Not specified: 0  
Recovered: 5048  
Resolved with Sequelae: 139  
Recovering: 4010  
Unknown: 1914  
Injured total 15529

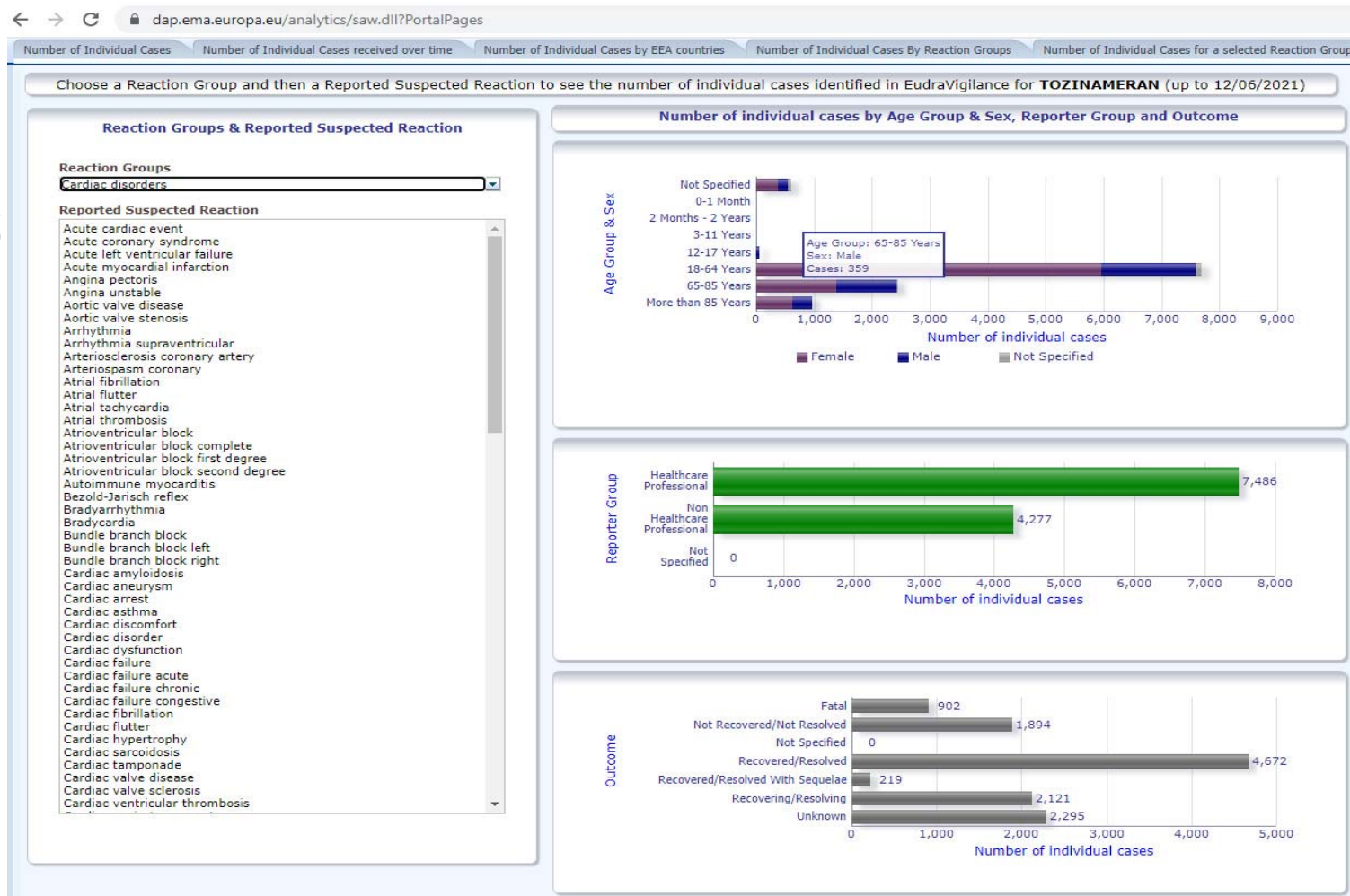
Pfizer 1/27



Reaction group 2:  
Cardiac disorders

Fatal: 902  
Not recovered: 1894  
Not specified: 0  
Recovered: 4672  
Resolved with Sequelae: 219  
Recovering: 2121  
Unknown: 2295  
Injured total 11201

Pfizer 2/27

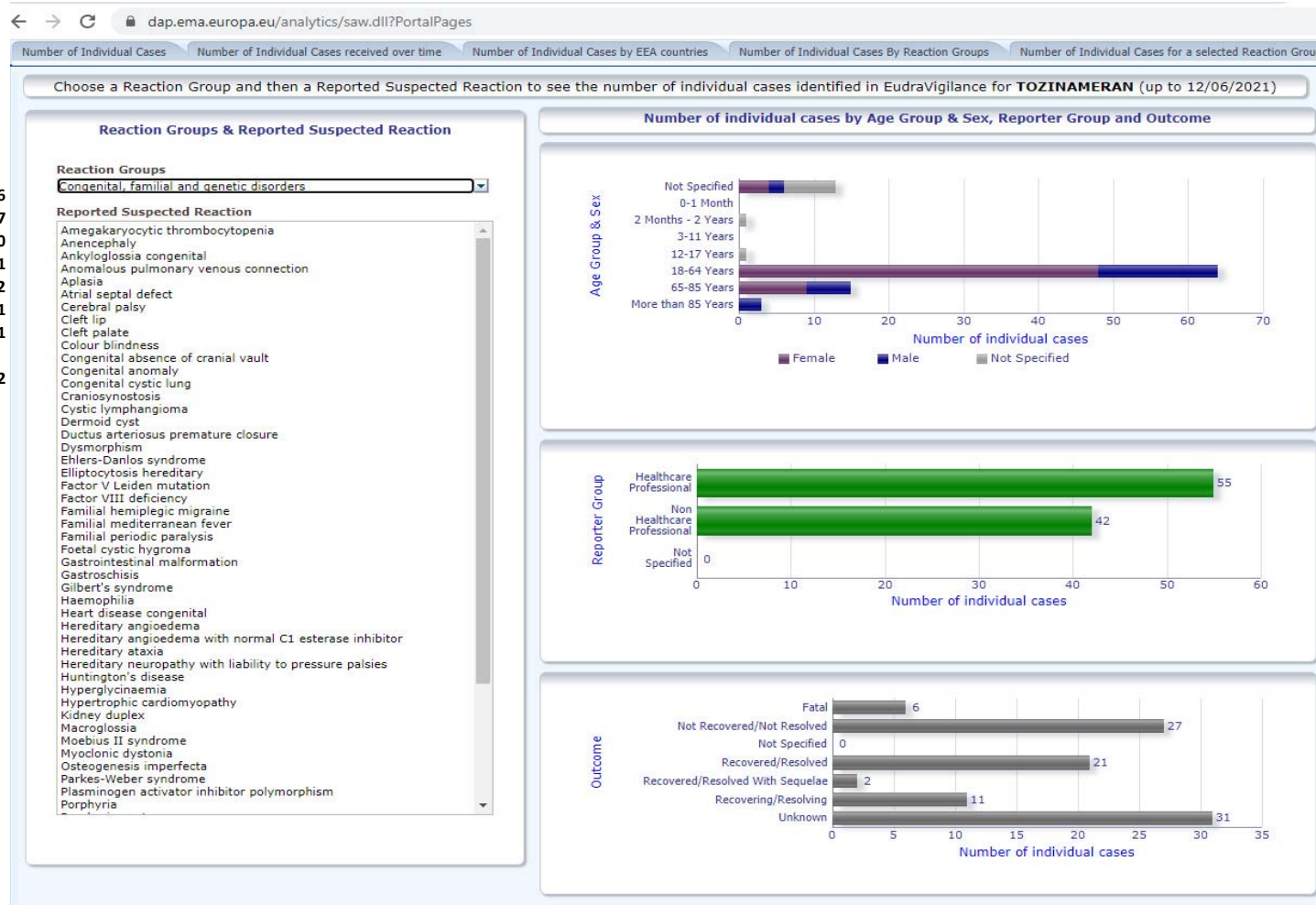


Reaction group 3:  
Congenital, familial and genetic disorders

Fatal:  
Not recovered:  
Not specified:  
Recovered:  
Resolved with Sequelae:  
Recovering:  
Unknown:  
Injured total

6  
27  
0  
21  
2  
11  
31  
92

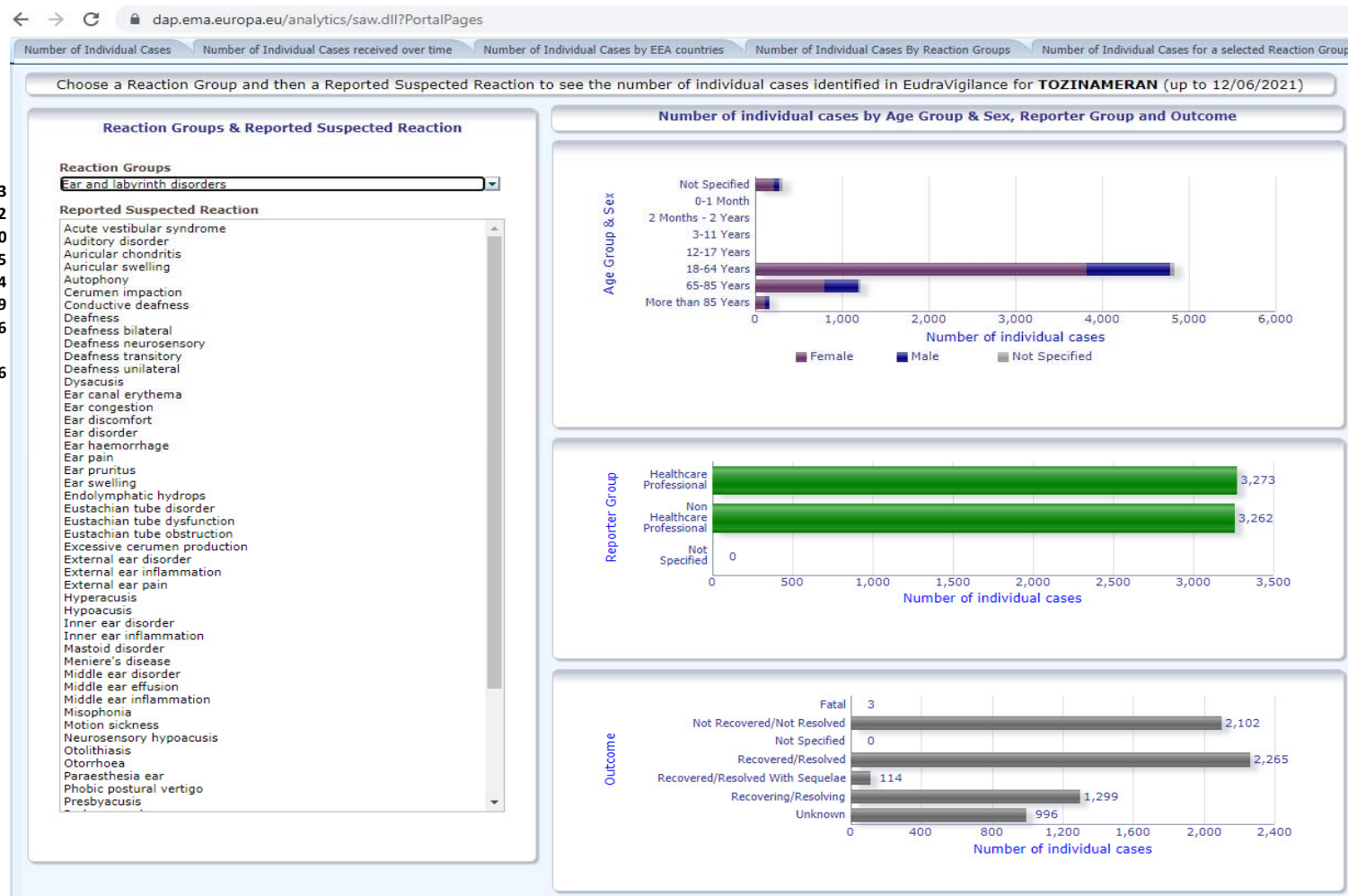
Pfizer 3/27



Reaction group 4:  
Ear and labyrinth disorders

Fatal: 3  
Not recovered: 2102  
Not specified: 0  
Recovered: 2265  
Resolved with Sequelae: 114  
Recovering: 1299  
Unknown: 996  
Injured total: 6776

Pfizer 4/27



Choose a Reaction Group and then a Reported Suspected Reaction to see the number of individual cases identified in EudraVigilance for **TOZINAMERAN** (up to 12/06/2021)

### Reaction Groups & Reported Suspected Reaction

#### Reaction Groups

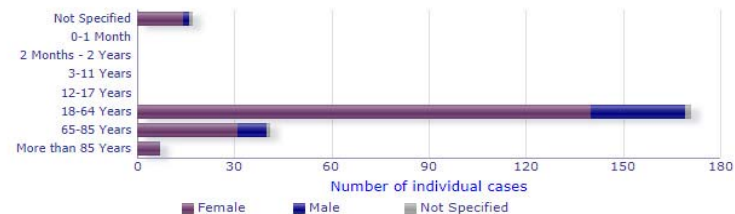
Endocrine disorders

#### Reported Suspected Reaction

Addison's disease  
Adrenal disorder  
Adrenal haemorrhage  
Adrenal insufficiency  
Adrenocortical insufficiency acute  
Adrenomegaly  
Anovulatory cycle  
Autoimmune hypothyroidism  
Autoimmune thyroid disorder  
Autoimmune thyroiditis  
Basedow's disease  
Cushingoid  
Diabetes insipidus  
Goitre  
Haemorrhagic thyroid cyst  
Hyperaldosteronism  
Hyperparathyroidism  
Hyperthyroidism  
Hypoparathyroidism  
Hypopituitarism  
Hypothyroidism  
Myxoedema  
Ovulation delayed  
Pituitary apoplexy  
Premature menarche  
Primary hyperaldosteronism  
Secondary adrenocortical insufficiency  
Silent thyroiditis  
Thyroid disorder  
Thyroid mass  
Thyroid pain  
Thyroiditis  
Thyroiditis acute  
Thyroiditis subacute  
Thyrotoxic crisis

### Number of individual cases by Age Group & Sex, Reporter Group and Outcome

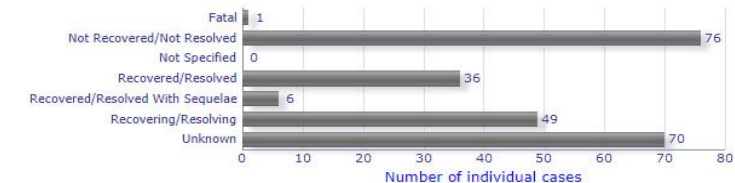
Age Group & Sex



Reporter Group



Outcome



Reaction group 5:  
Endocrine disorders

Fatal: 1  
Not recovered: 76  
Not specified: 0  
Recovered: 36  
Resolved with Sequelae: 6  
Recovering: 49  
Unknown: 70  
Injured total: 237

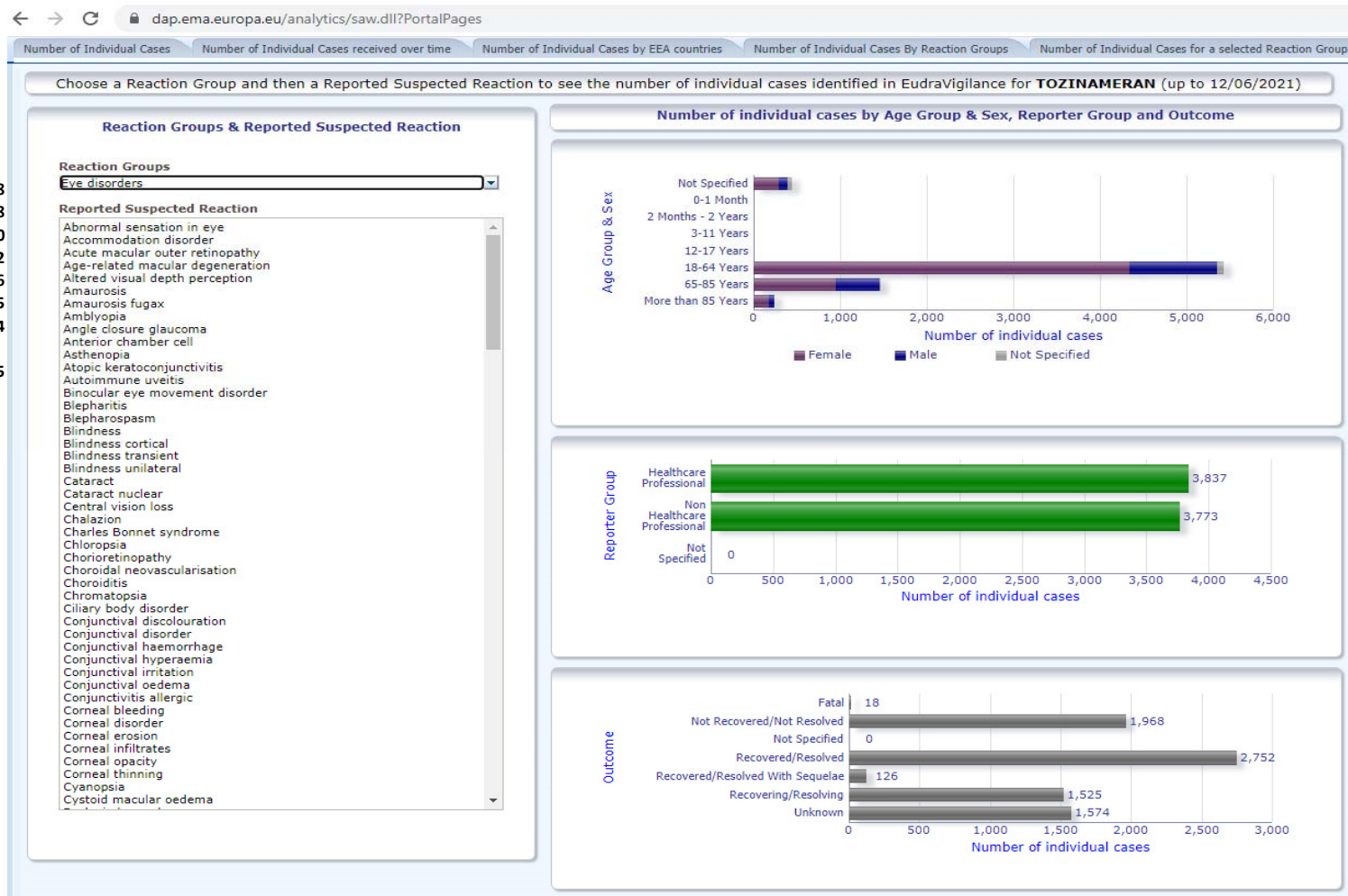
Pfizer 5/27



Reaction group 6:  
Eye disorders

Fatal: 18  
Not recovered: 1968  
Not specified: 0  
Recovered: 2752  
Resolved with Sequelae: 126  
Recovering: 1525  
Unknown: 1574  
Injured total 7945

Pfizer 6/27



Choose a Reaction Group and then a Reported Suspected Reaction to see the number of individual cases identified in EudraVigilance for **TOZINAMERAN** (up to 12/06/2021)

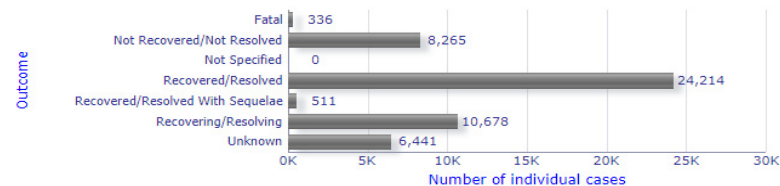
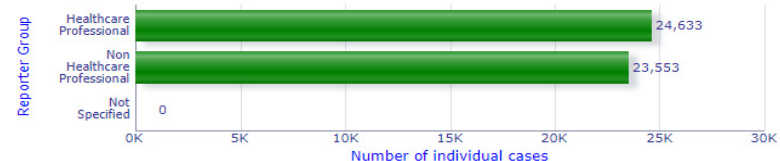
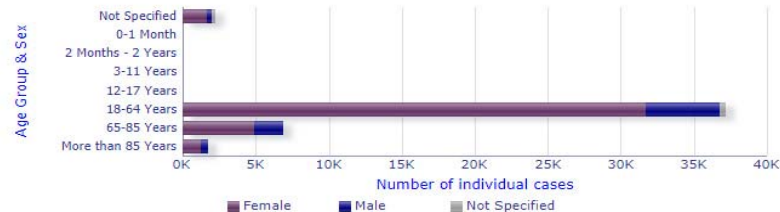
Reaction group 7:  
Gastrointestinal disorders

Fatal: 336  
Not recovered: 8265  
Not specified: 0  
Recovered: 24214  
Resolved with Sequelae: 511  
Recovering: 10678  
Unknown: 6441  
Injured total 50109

### Reaction Groups & Reported Suspected Reaction

- Reaction Groups  
Gastrointestinal disorders
- Reported Suspected Reaction
- Abdominal adhesions
  - Abdominal discomfort
  - Abdominal distension
  - Abdominal mass
  - Abdominal migraine
  - Abdominal pain
  - Abdominal pain lower
  - Abdominal pain upper
  - Abdominal rigidity
  - Abdominal symptom
  - Abdominal tenderness
  - Abdominal wall haematoma
  - Abdominal wall haemorrhage
  - Abdominal wall oedema
  - Abnormal faeces
  - Acetonaemic vomiting
  - Acquired macroglossia
  - Acute abdomen
  - Aerophagia
  - Allergic gastroenteritis
  - Anaesthesia oral
  - Anal fissure
  - Anal fistula
  - Anal haemorrhage
  - Anal hypoaesthesia
  - Anal incontinence
  - Anal inflammation
  - Anal pruritus
  - Anal rash
  - Anal sphincter atony
  - Anal sphincter hypertonia
  - Angina bullosa haemorrhagica
  - Angular cheilitis
  - Anorectal discomfort
  - Anorectal swelling
  - Aphthous ulcer
  - Appendix disorder
  - Aptyalism
  - Ascites
  - Atrophic glossitis
  - Autoimmune pancreatitis
  - Barrett's oesophagus
  - Bowel movement irregularity
  - Breath odour
  - Burning mouth syndrome
  - Cardiospasm

### Number of individual cases by Age Group & Sex, Reporter Group and Outcome

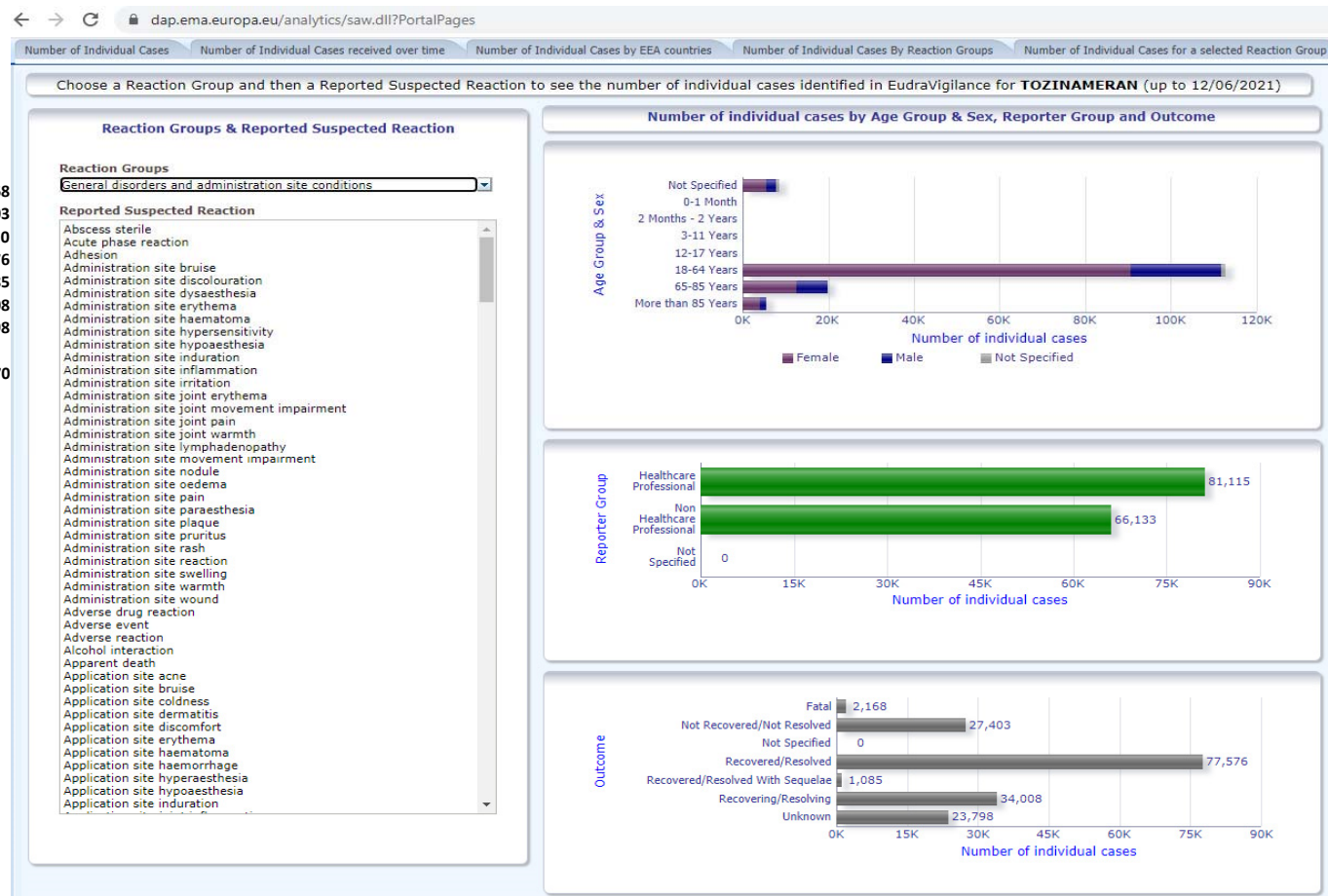


Pfizer 7/27

Reaction group 8:  
General disorders and administration site conditions

Fatal: 2168  
Not recovered: 27403  
Not specified: 0  
Recovered: 77576  
Resolved with Sequelae: 1085  
Recovering: 34008  
Unknown: 23798  
Injured total 163870

Pfizer 8/27

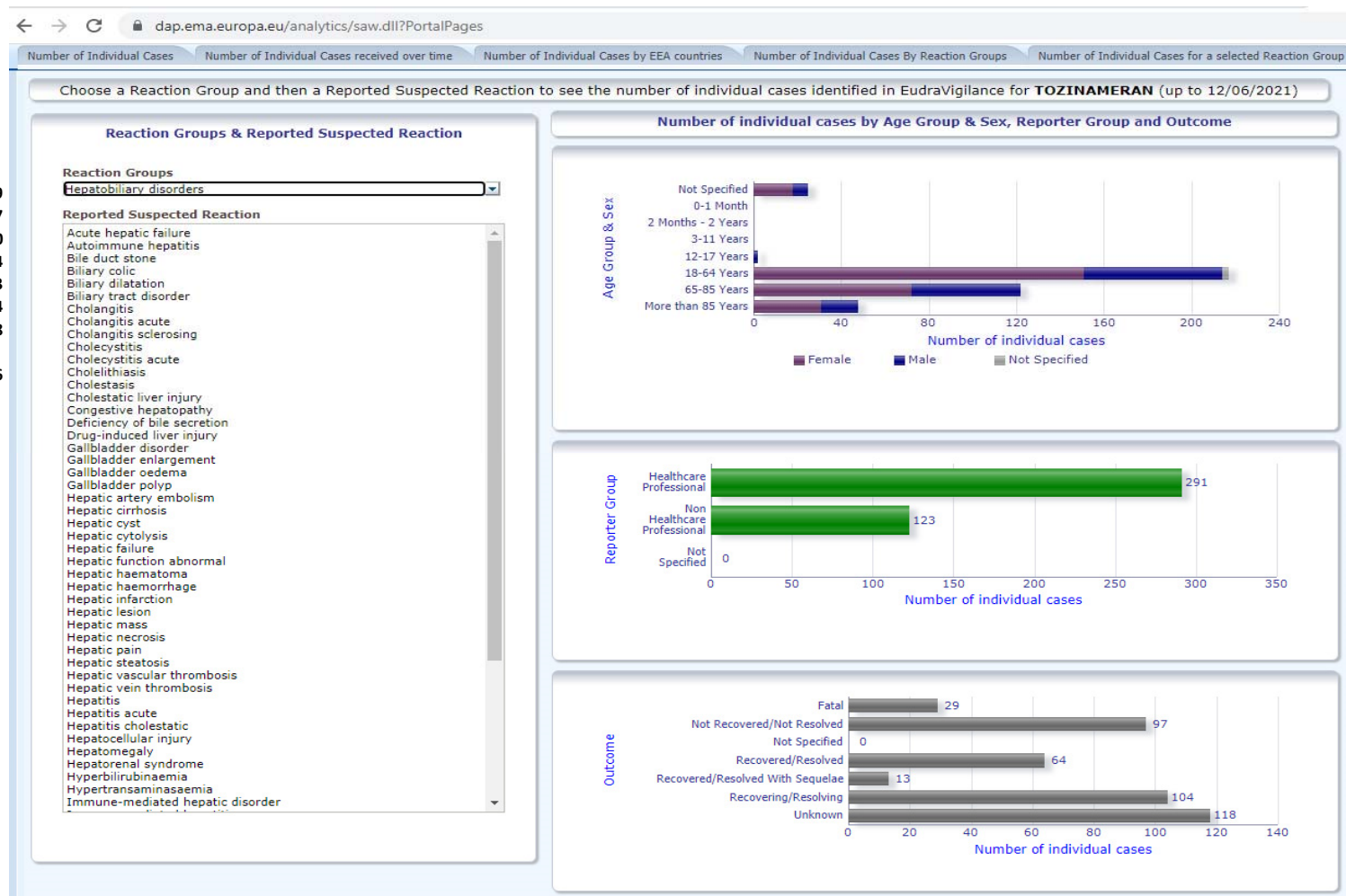




Reaction group 9:  
Hepatobiliary disorders

Fatal: 29  
Not recovered: 97  
Not specified: 0  
Recovered: 64  
Resolved with Sequelae: 13  
Recovering: 104  
Unknown: 118  
  
Injured total 396

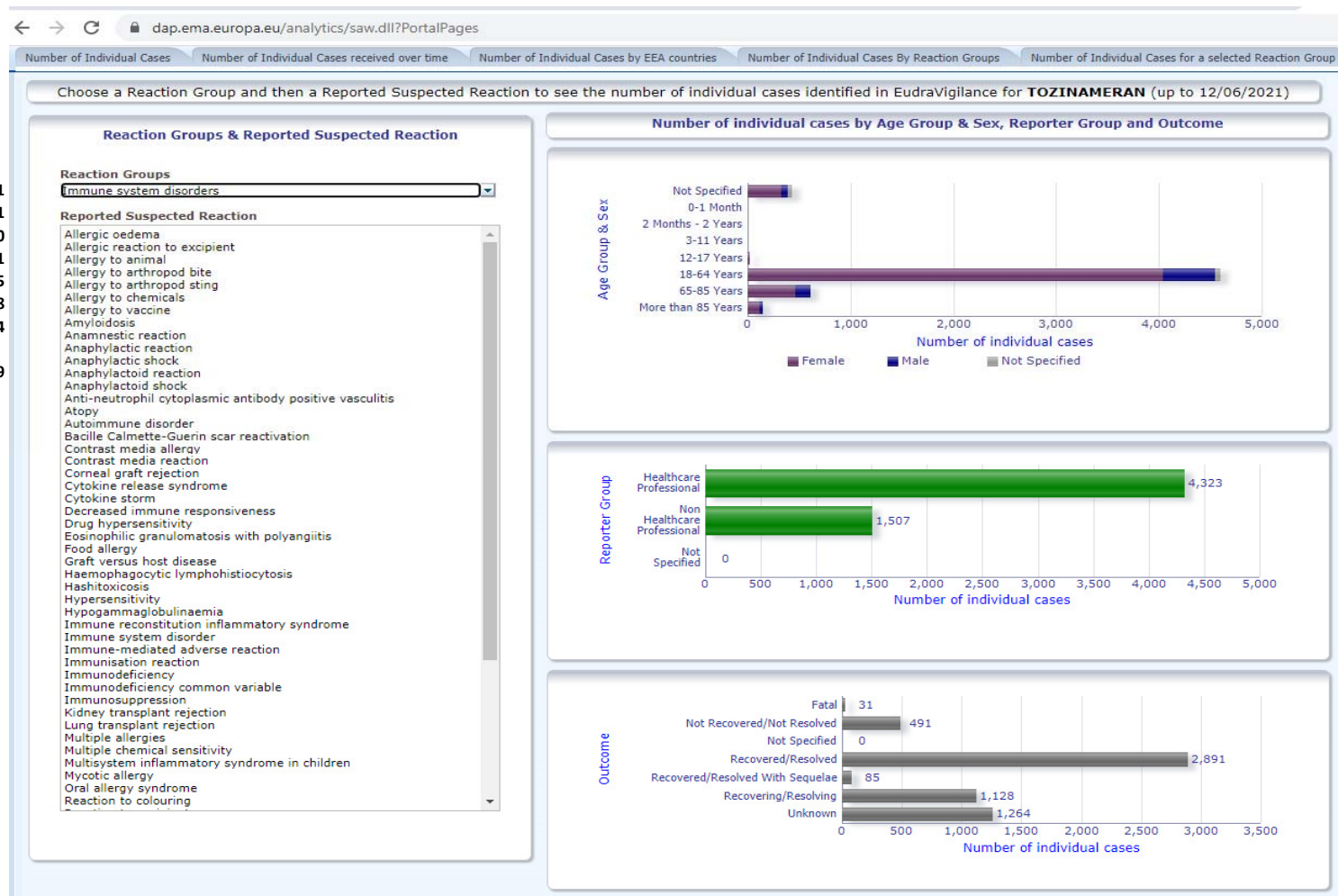
Pfizer 9/27



Reaction group 10:  
Immune system disorders

Fatal: 31  
Not recovered: 491  
Not specified: 0  
Recovered: 2891  
Resolved with Sequelae: 85  
Recovering: 1128  
Unknown: 1264  
Injured total: 5859

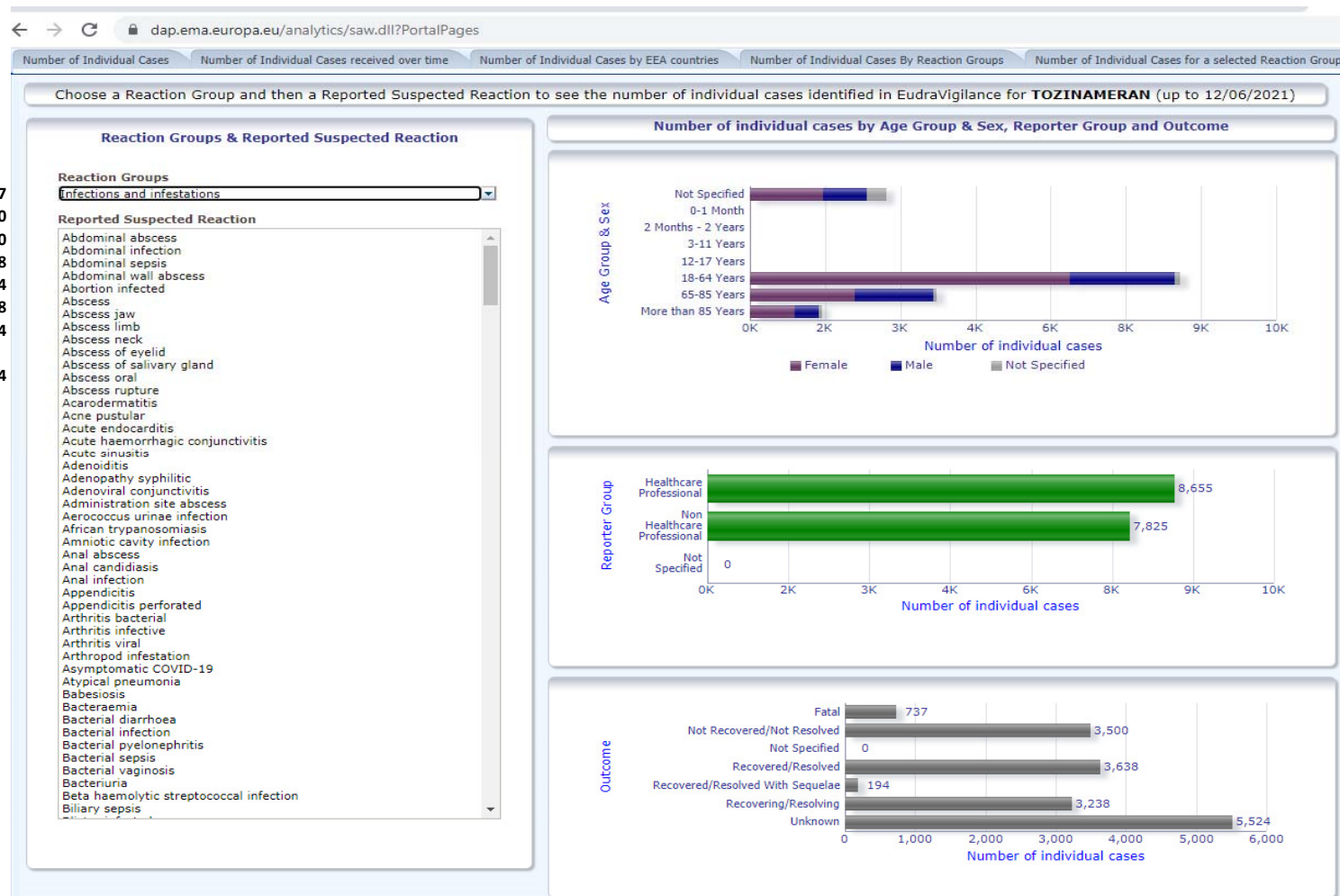
Pfizer 10/27



Reaction group 11:  
Infections and infestations

Fatal: 737  
Not recovered: 3500  
Not specified: 0  
Recovered: 3638  
Resolved with Sequelae: 194  
Recovering: 3238  
Unknown: 5524  
  
Injured total 16094

Pfizer 11/27



Choose a Reaction Group and then a Reported Suspected Reaction to see the number of individual cases identified in EudraVigilance for **TOZINAMERAN** (up to 12/06/2021)

### Reaction Groups & Reported Suspected Reaction

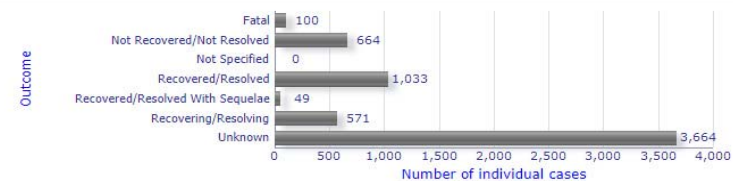
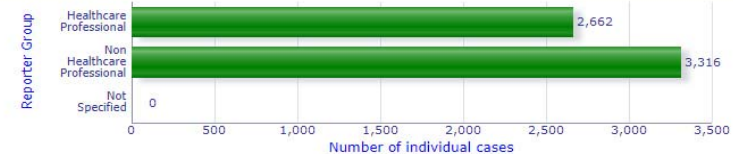
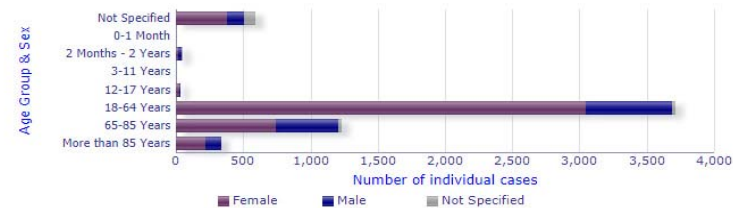
#### Reaction Groups

Injury, poisoning and procedural complications

#### Reported Suspected Reaction

Accident  
Accidental exposure to product  
Accidental overdose  
Adverse event following immunisation  
Airway burns  
Airway complication of anaesthesia  
Alcohol poisoning  
Anaesthetic complication  
Animal bite  
Ankle fracture  
Arteriovenous fistula thrombosis  
Arteriovenous graft thrombosis  
Arthropod bite  
Arthropod sting  
Atypical femur fracture  
Autonomic dysreflexia  
Back injury  
Barotrauma  
Bite  
Bone contusion  
Bone fragmentation  
Booster dose missed  
Brachial plexus injury  
Brain contusion  
Brain herniation  
Burn oesophageal  
Burn of internal organs  
Burn oral cavity  
Burns second degree  
Burns third degree  
Cartilage injury  
Central cord syndrome  
Cervical vertebral fracture  
Chest crushing  
Chest injury  
Chillblains  
Circumstance or information capable of leading to medication error  
Clavicle fracture  
Cold burn  
Compression fracture  
Concussion  
Conjunctival laceration  
Contraindicated product administered  
Contraindicated product prescribed  
Contusion  
Corneal abrasion

### Number of individual cases by Age Group & Sex, Reporter Group and Outcome



Reaction group 12:  
Injury, poisoning and procedural complications

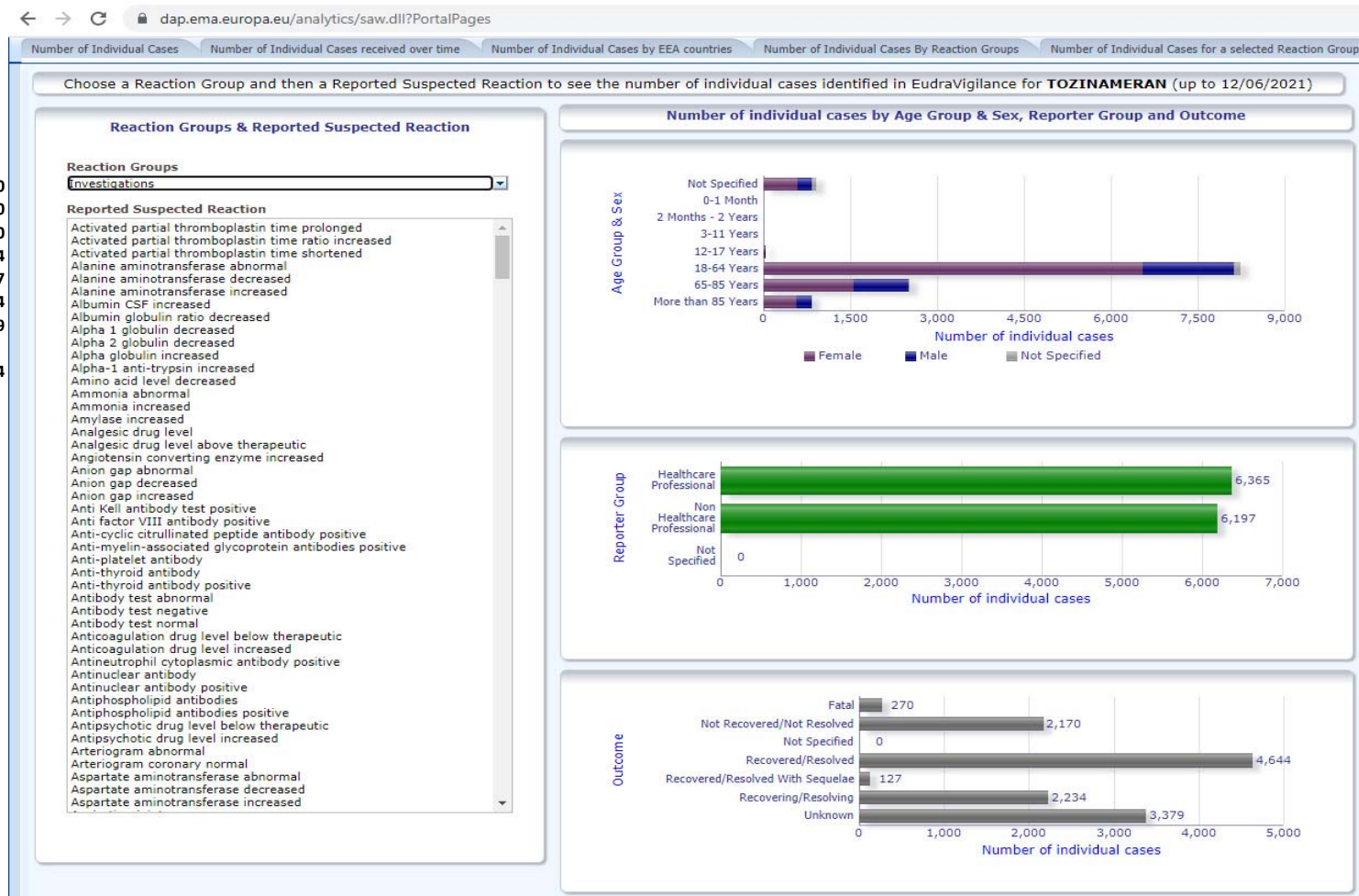
Fatal: 100  
Not recovered: 664  
Not specified: 0  
Recovered: 1033  
Resolved with Sequelae: 49  
Recovering: 571  
Unknown: 3664  
  
Injured total 5981

Pfizer 12/27

Reaction group 13:  
Investigations

Fatal: 270  
Not recovered: 2170  
Not specified: 0  
Recovered: 4644  
Resolved with Sequelae: 127  
Recovering: 2234  
Unknown: 3379  
Injured total 12554

Pfizer 13/27

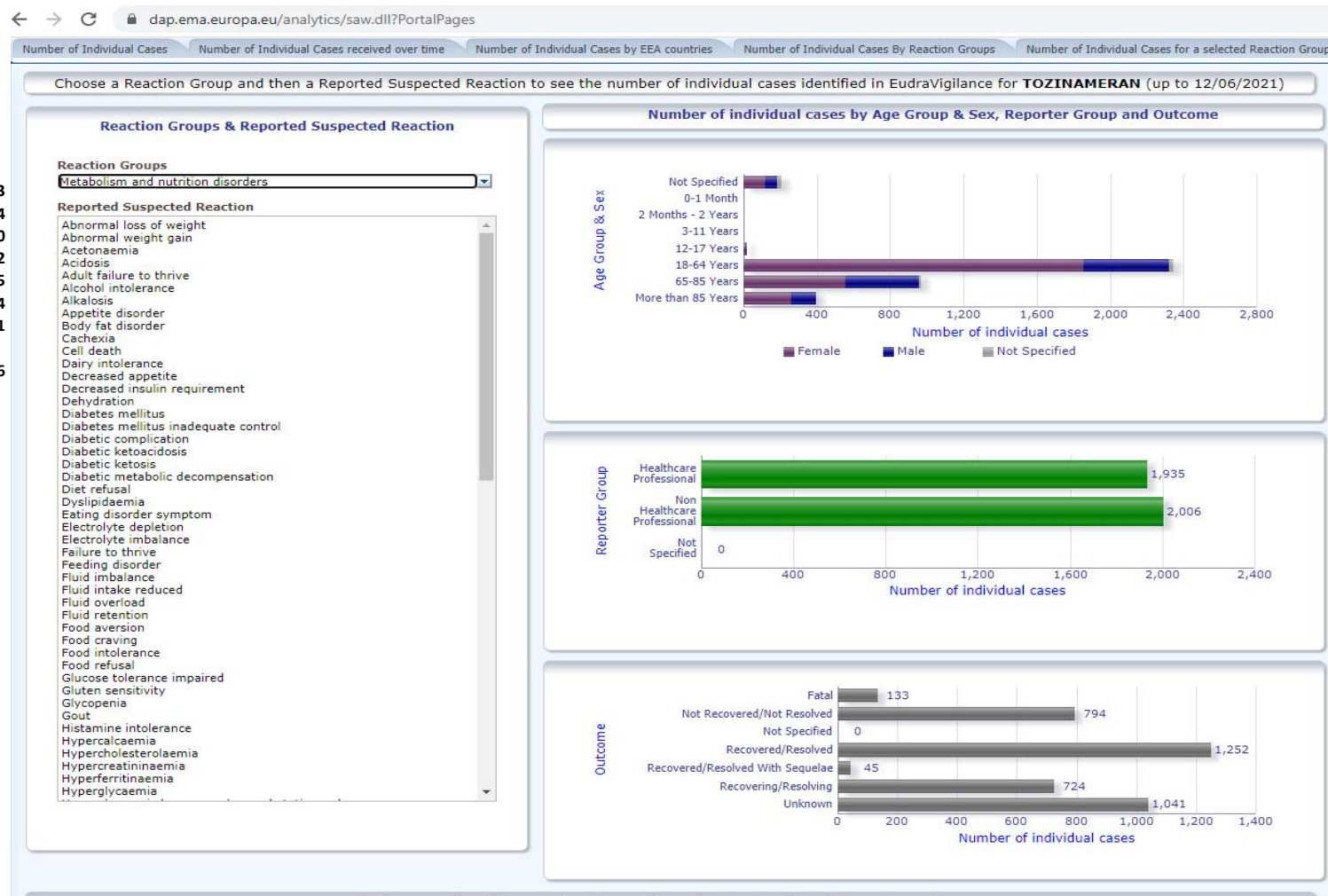




Reaction group 14:  
Metabolism and nutrition disorders

Fatal: 133  
Not recovered: 794  
Not specified: 0  
Recovered: 1252  
Resolved with Sequelae: 45  
Recovering: 724  
Unknown: 1041  
Injured total 3856

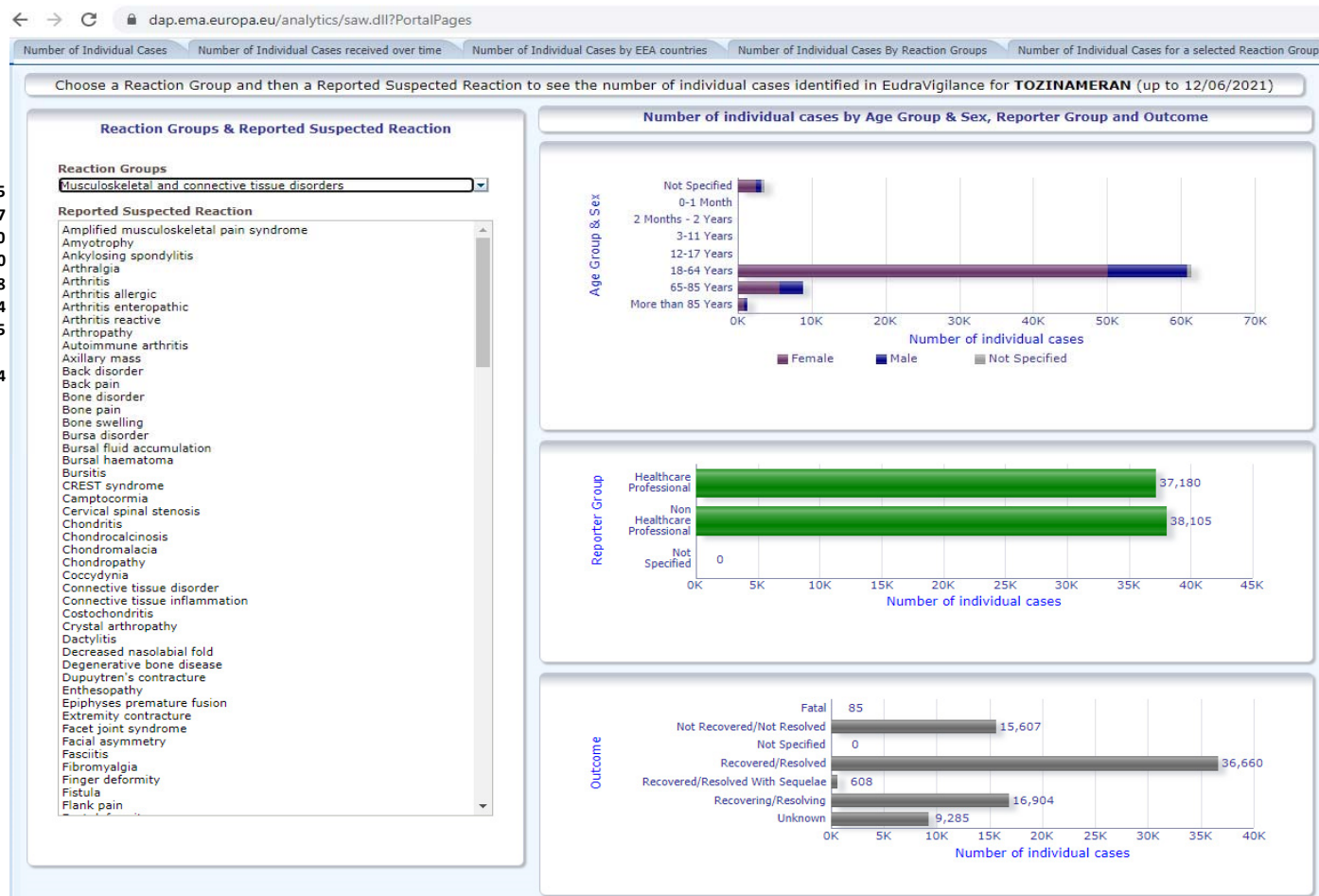
Pfizer 14/27



Reaction group 15:  
Musculoskeletal and connective tissue disorders

Fatal: 85  
Not recovered: 15607  
Not specified: 0  
Recovered: 36660  
Resolved with Sequelae: 608  
Recovering: 16904  
Unknown: 9285  
Injured total 79064

Pfizer 15/27



Reaction group 16:  
Neoplasms benign, malignant and unspecified

Fatal: 22  
Not recovered: 83  
Not specified: 0  
Recovered: 22  
Resolved with Sequelae: 6  
Recovering: 27  
Unknown: 150  
Injured total 288

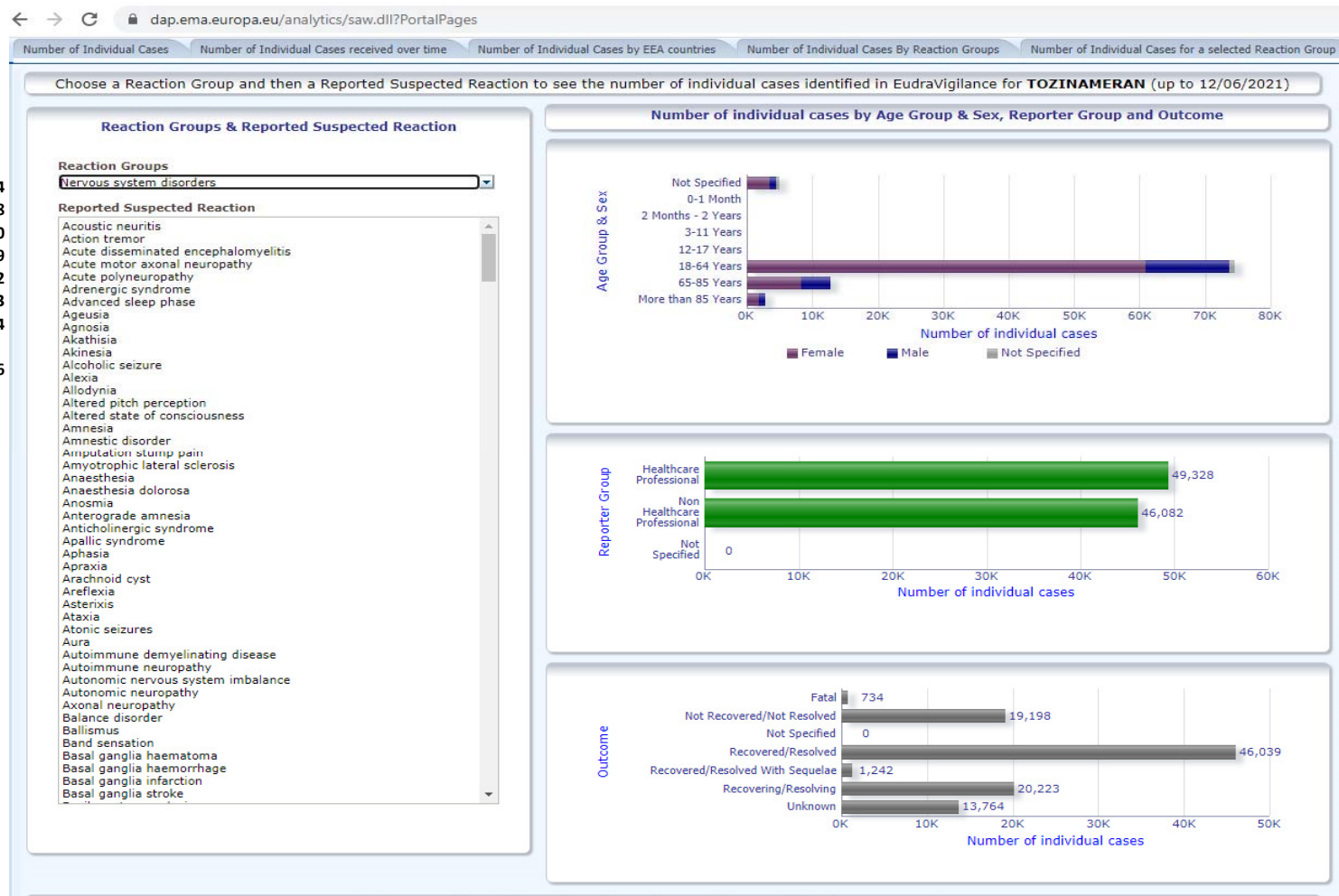
Pfizer 16/27



Reaction group 17:  
Nervous system disorders

Fatal: 734  
Not recovered: 19198  
Not specified: 0  
Recovered: 46039  
Resolved with Sequelae: 1242  
Recovering: 20223  
Unknown: 13764  
Injured total 100466

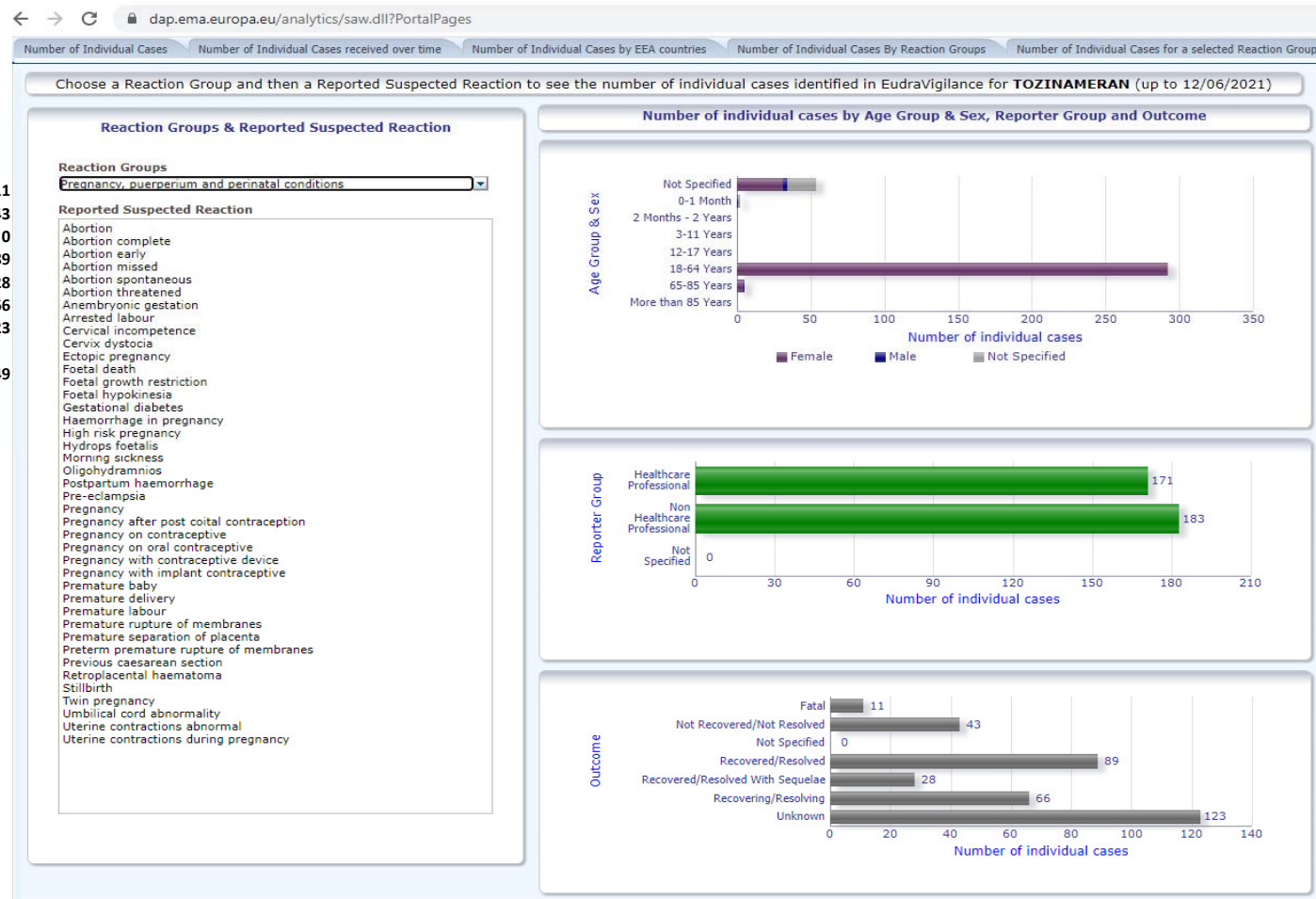
Pfizer 17/27



Reaction group 18:  
Pregnancy, puerperium and perinatal conditions

Fatal: 11  
Not recovered: 43  
Not specified: 0  
Recovered: 89  
Resolved with Sequelae: 28  
Recovering: 66  
Unknown: 123  
Injured total 349

Pfizer 18/27





Reaction group 19:  
Product issues

Fatal: 0  
Not recovered: 11  
Not specified: 0  
Recovered: 12  
Resolved with Sequelae: 0  
Recovering: 7  
Unknown: 72  
Injured total 102

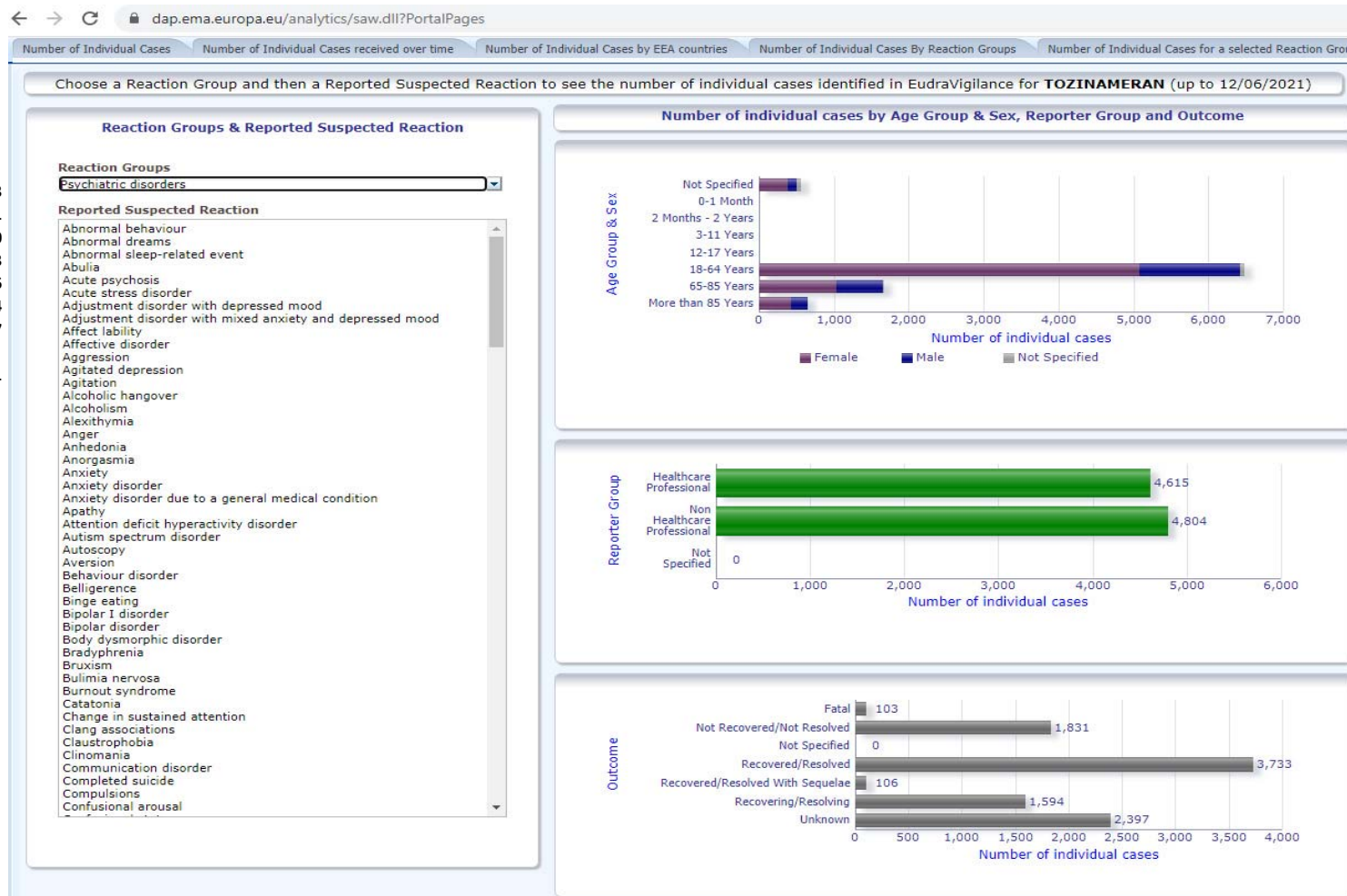
Pfizer 19/27

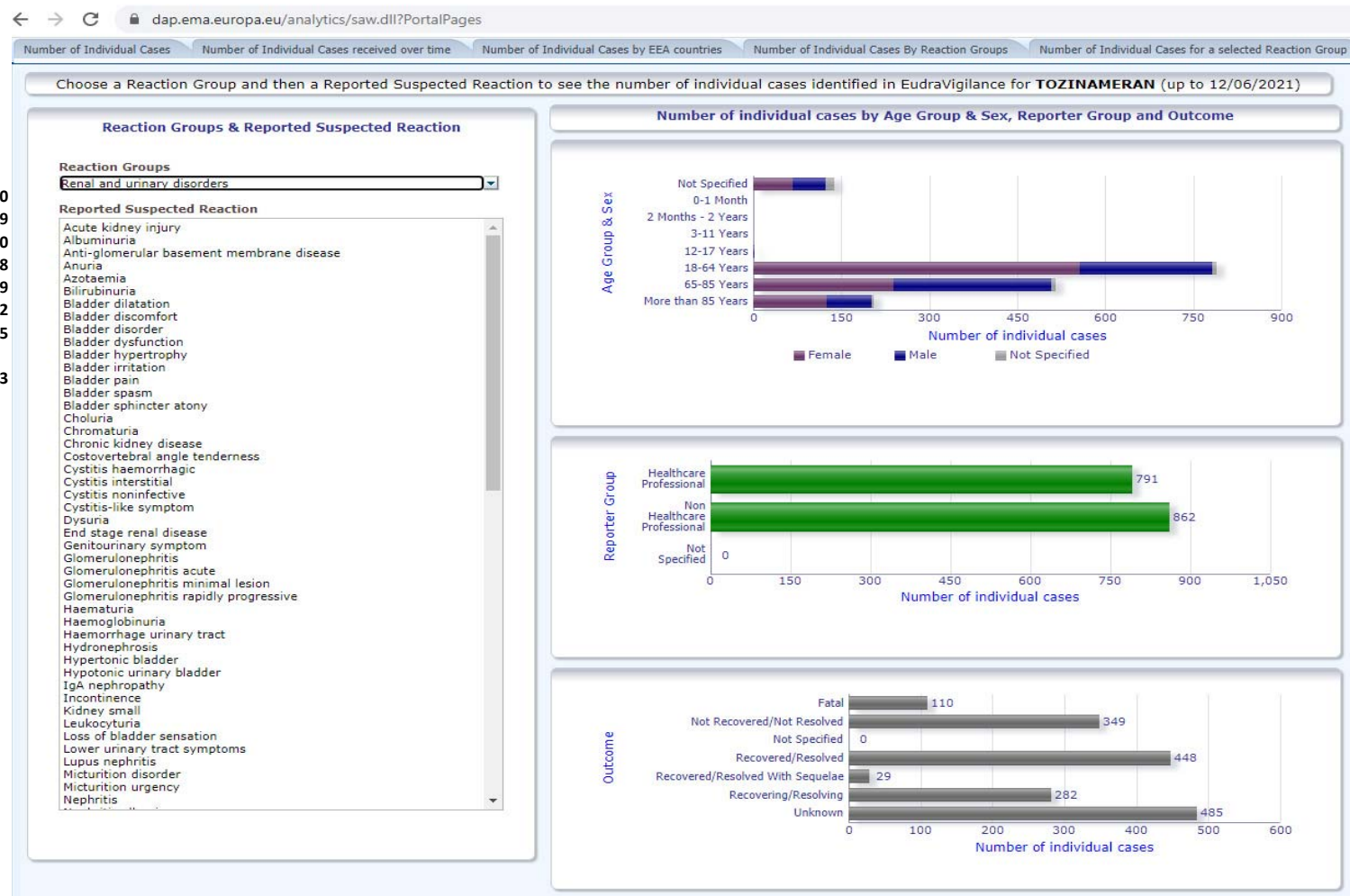


Reaction group 20:  
Psychiatric disorders

Fatal: 103  
Not recovered: 1831  
Not specified: 0  
Recovered: 3733  
Resolved with Sequelae: 106  
Recovering: 1594  
Unknown: 2397  
Injured total 9661

Pfizer 20/27





Reaction group 21:  
Renal and urinary disorders

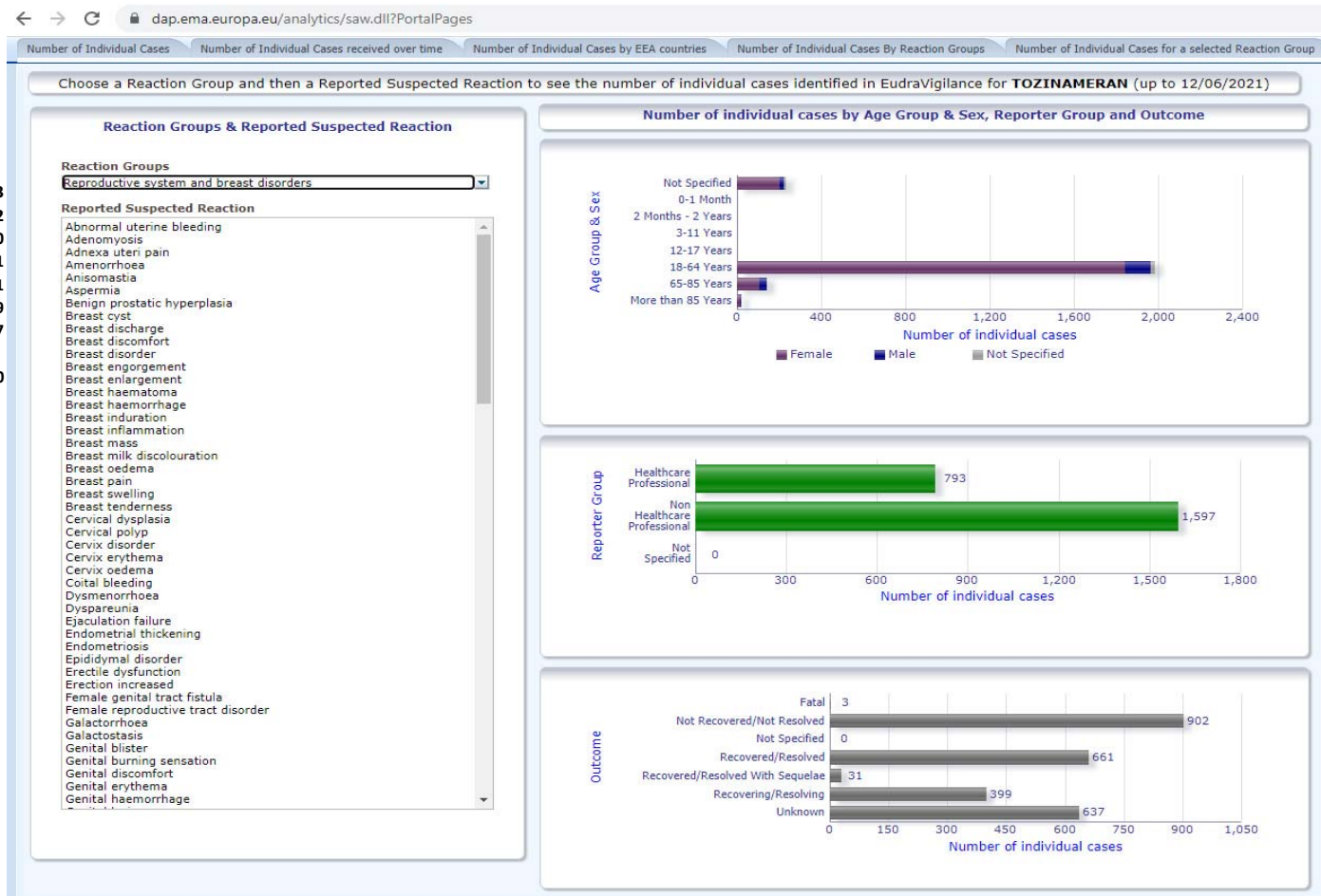
Fatal: 110  
Not recovered: 349  
Not specified: 0  
Recovered: 448  
Resolved with Sequelae: 29  
Recovering: 282  
Unknown: 485  
Injured total: 1593

Pfizer 21/27

Reaction group 22:  
Reproductive system and breast disorders

Fatal: 3  
Not recovered: 902  
Not specified: 0  
Recovered: 661  
Resolved with Sequelae: 31  
Recovering: 399  
Unknown: 637  
  
Injured total 2630

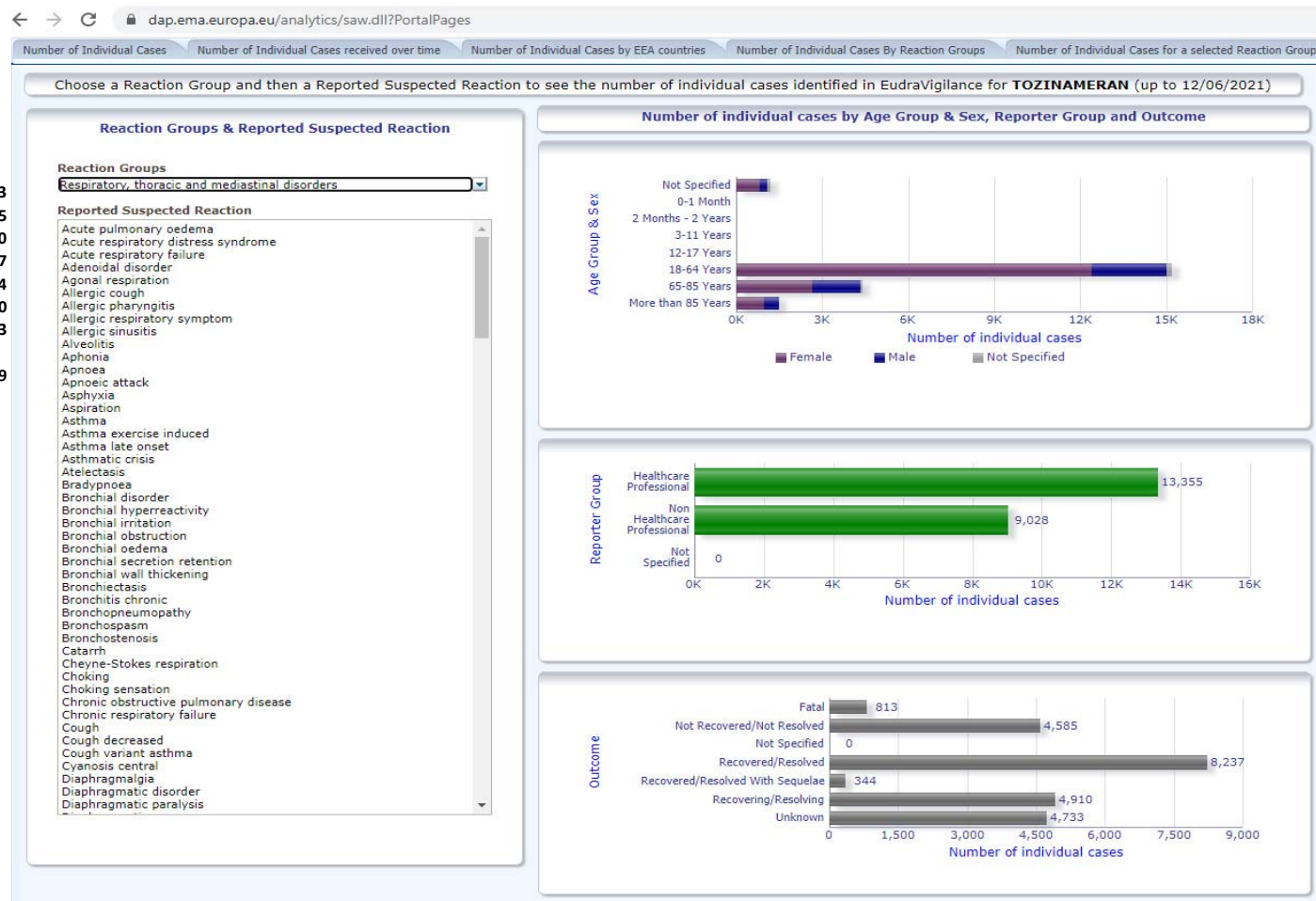
Pfizer 22/27



Reaction group 23:  
Respiratory, thoracic and mediastinal disorders

Fatal: 813  
Not recovered: 4585  
Not specified: 0  
Recovered: 8237  
Resolved with Sequelae: 344  
Recovering: 4910  
Unknown: 4733  
  
Injured total 22809

Pfizer 23/27

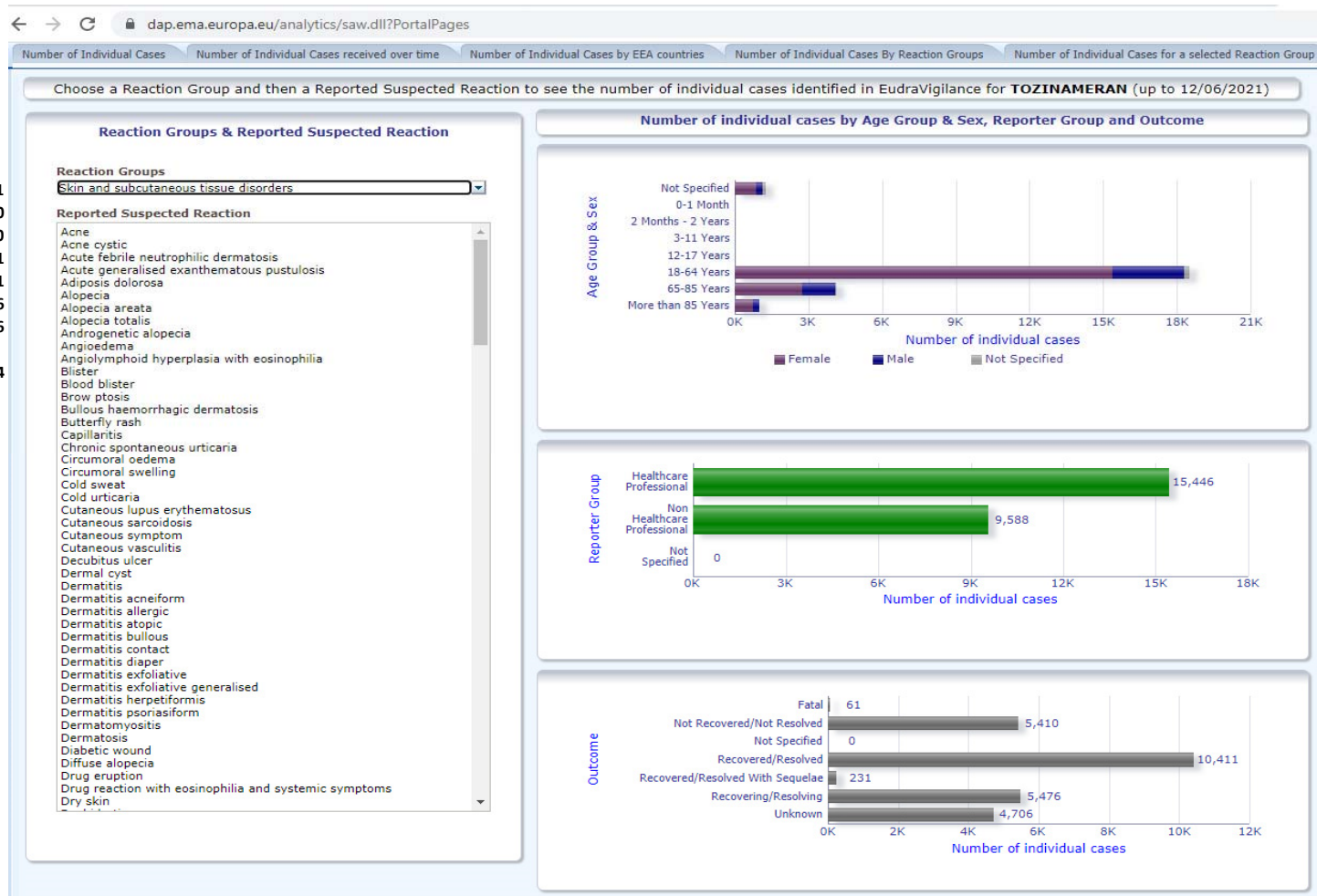




Reaction group 24:  
Skin and subcutaneous tissue disorders

Fatal: 61  
Not recovered: 5410  
Not specified: 0  
Recovered: 10411  
Resolved with Sequelae: 231  
Recovering: 5476  
Unknown: 4706  
Injured total 26234

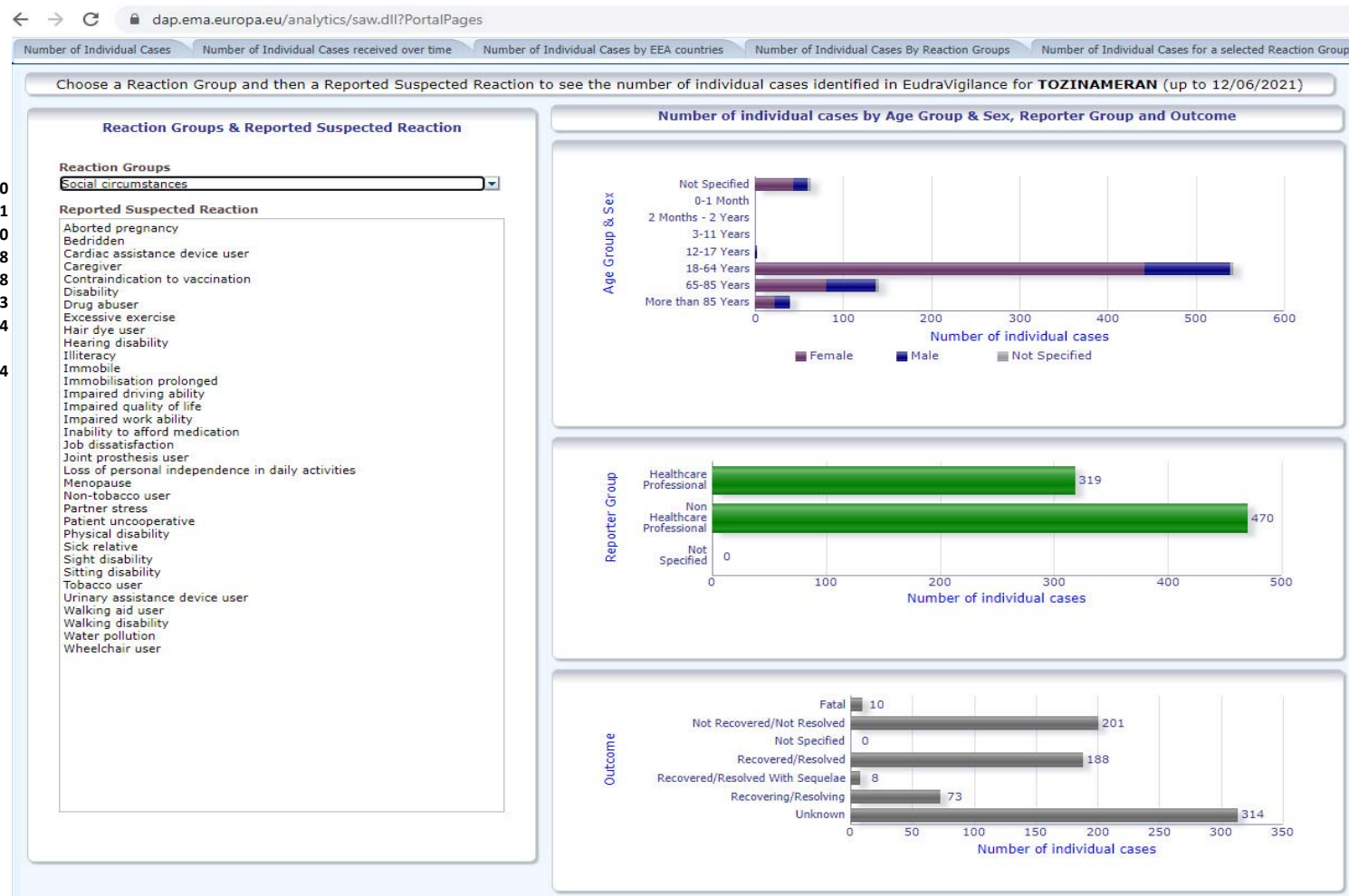
Pfizer 24/27



Reaction group 25:  
Social circumstances

Fatal: 10  
Not recovered: 201  
Not specified: 0  
Recovered: 188  
Resolved with Sequelae: 8  
Recovering: 73  
Unknown: 314  
  
Injured total 784

Pfizer 25/27



Reaction group 26:  
Surgical and medical procedures

Fatal: 17  
Not recovered: 54  
Not specified: 0  
Recovered: 81  
Resolved with Sequelae: 11  
Recovering: 51  
Unknown: 39  
  
Injured total 236

Pfizer 26/27



Reaction group 27:  
Vascular disorders

Fatal: 272  
Not recovered: 2606  
Not specified: 0  
Recovered: 5323  
Resolved with Sequelae: 199  
Recovering: 2868  
Unknown: 2726  
Injured total 13722

Pfizer 27/27



<b>Pfizer Total</b>	
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<b>Total Fatal:</b>	<b>7054</b>
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<b>Total injured:</b>	<b>558437</b>
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