JAZMP

Information support for pharmacovigilance in human medicine at national level

Presentation of the project

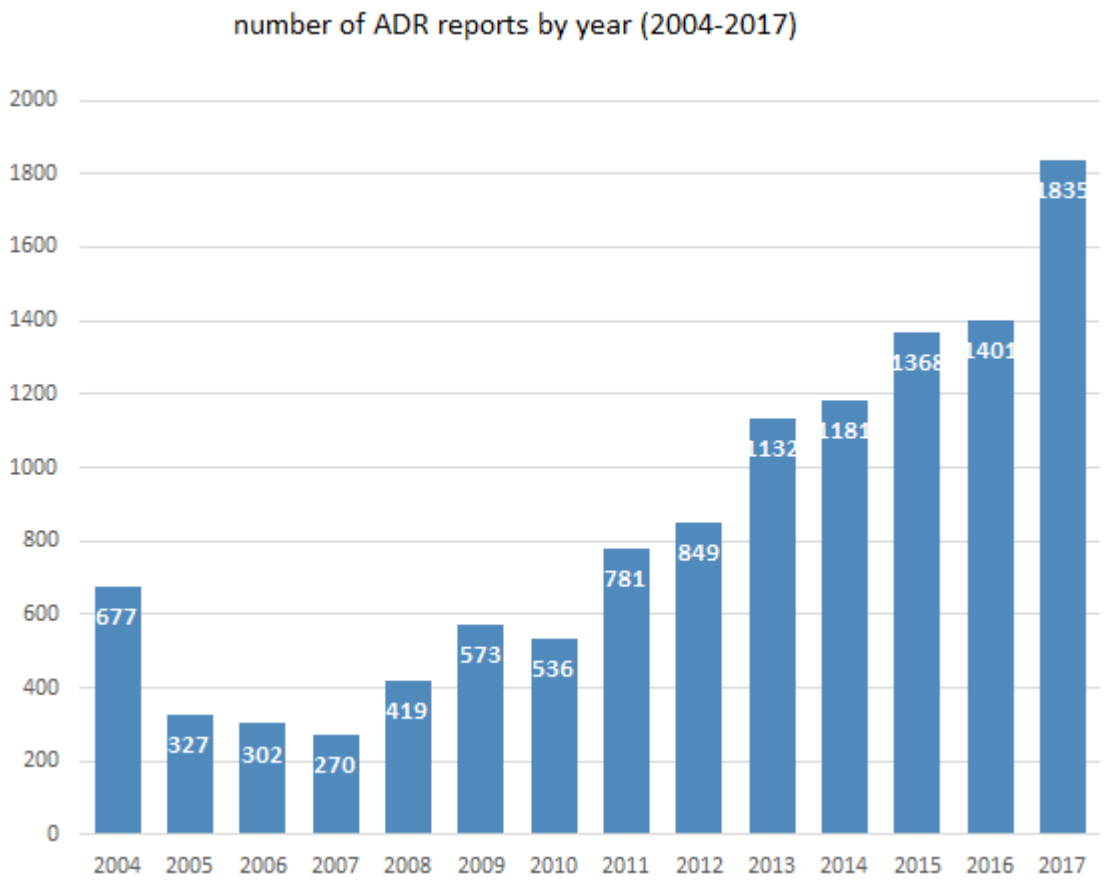
The importance of ADR reporting

- Reports of suspected ADRs are an important source of data for the detection of new safety signals and potential changes in known risks
- The reports are transmitted to the EU database EudraVigilance and to the WHO VigiBase database and are included in the safety monitoring of medicines
- Each ADR report is important and contributes to safer use of medicines
- In systematic reviews of ADR reporting, a high non-reporting rate (76%, even 95%), including serious ADRs, was found for reasons like. eg ignorance, self-sufficiency, uncertainty about NUZ, the belief that only safe medicines, lack of interest or time to look for a form are on the market, the view that one case does not contribute to clinical knowledge ....
- Reporting is greatly influenced by the knowledge and attitude of a healthcare professional to reporting

Reporting data in Slovenia

Primary source:

Pysician: 68,3%
Pharmacist: 10,0%
Other health professional: 3,5%
Patient: 11,7%
Other: literature reports



Summary of the Mediately Research Research, September 2017

- In the overall results of the survey, 65% of doctors have never reported suspected adverse drug reactions, with only 5% of doctors regularly doing this (five times or more).
- The main factors that discourage doctors from reporting are ignorance of the reporting process (43% of doctors) and the lack of reporting time (40%), and uncertainty is also important factors in which cases (32%) and the overly complicated reporting process (23%) are reported.
- Factors that encourage or encourage reporting are easier access to the online or mobile phone reporting process (59% of doctors), feedback on reports (53%), and a faster or simpler reporting process (52%).
- As the primary purpose of the report, doctors understand the withdrawal of hazardous medicines from sales (68% of doctors) and the detection of previously unknown adverse reactions (64%).

How to cope with the challenges?

- Reporting of ADR in the case of a suitably developed software solution can be improved with an electronic application form.
- This can be self-contained or, in the case of suitably developed software solutions, integrated into (clinical) information systems of healthcare providers.
- A study conducted by Ribeiro-Vazova et al. Showed that the use of an electronic form and awareness-raising of hospital health professionals significantly increased the number of reports. The number of reported ADRs in 18 Portuguese hospitals was increased by 3 times after the introduction of the system and 4.5 other adverse reactions

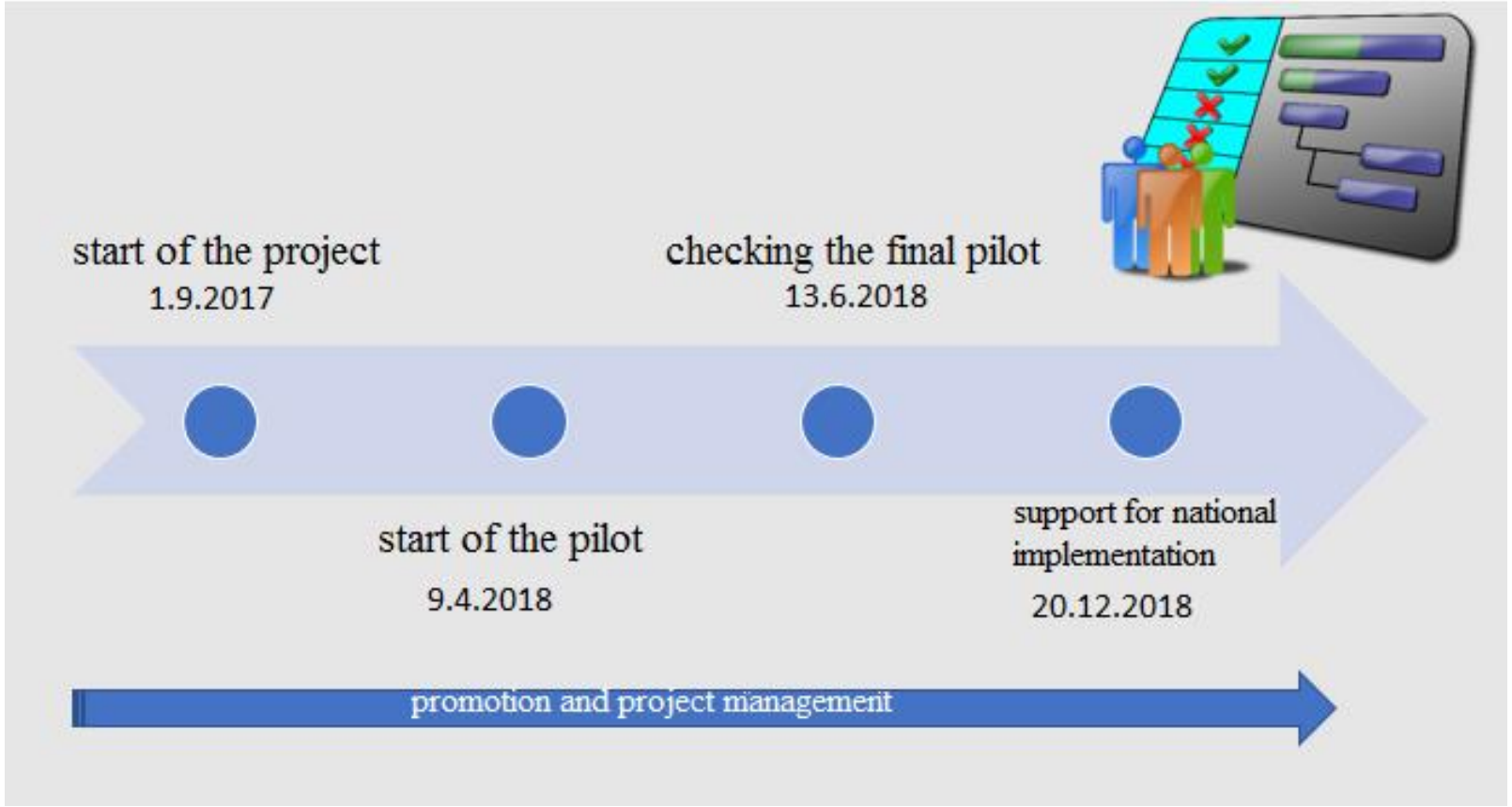
Current situation and disadvantages

- A variety of software solutions cause confusion and higher costs.
- No structured links to backend systems.
- About NUZ is reported in several formats.
- Manually overwriting data at reporters and at JAZMP.

Project goals

- Digitize the registration and treatment of ADR without transcribing data and consequently.
- Increase the number of ADR applications by establishing effective IT support
- Simplify and speed up the processing of ADR reports

Time milestones of the project



The objectives of the pilot project

Establishment of electronic transmission of reports of suspected ADRs from information systems of healthcare providers in different environments

- Create a friendly and easy user interface for reporting as many pre-retrieved data as the ADR report from backend systems
- Verify and supplement user and technical instructions for e-transmission of ADR
- Check the VigiFlow JAZMP application
- Encourage the development and introduction of inf. support in different environments of health care providers

Pilot project activities

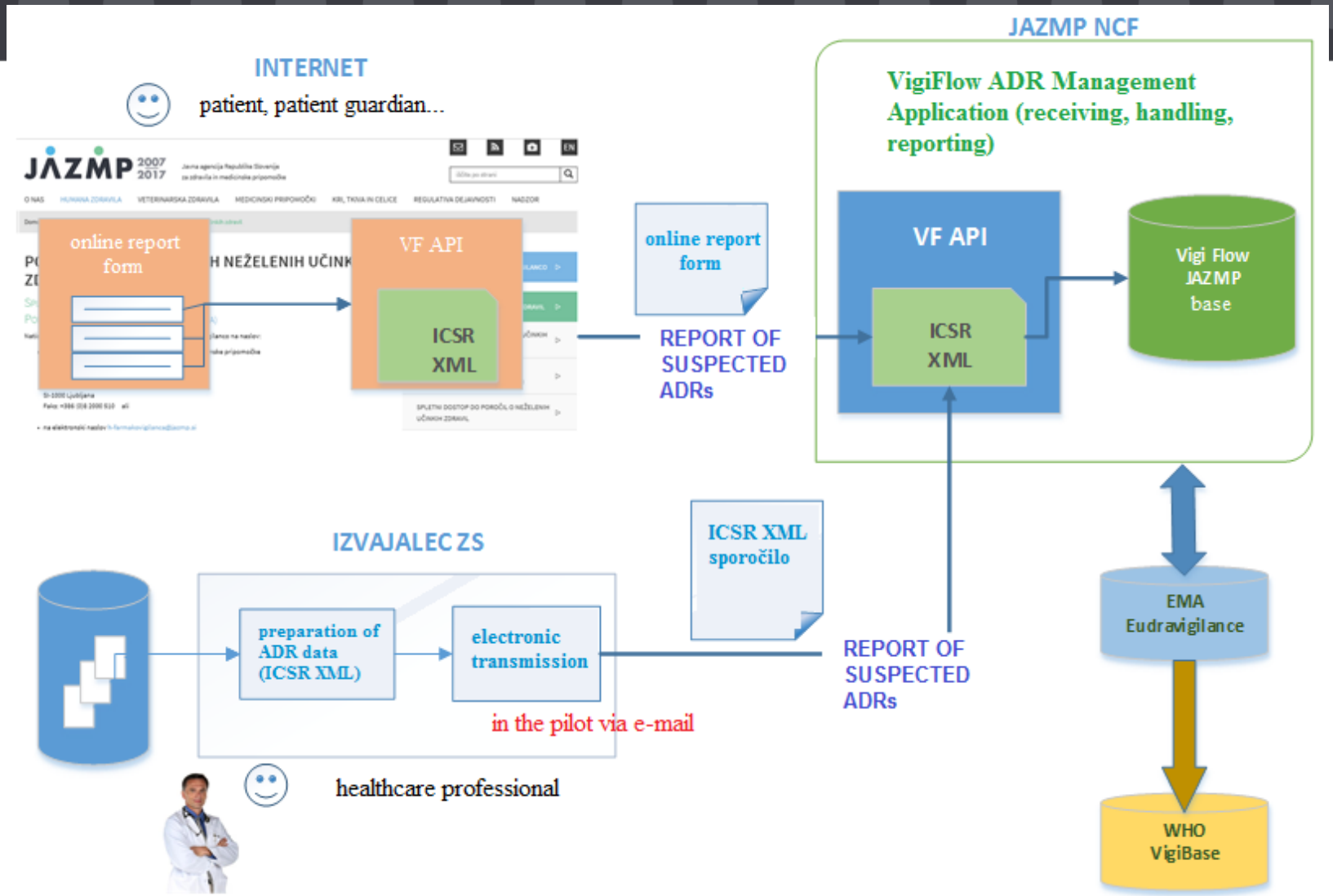
- Harmonization and signing of the cooperation agreement
- Creation of a content implementation plan and agreement with the software house on the technical implementation
- Development of additional functionality in the backend information system
- Handling, coordinating and supplementing the instructions
- Testing the import of prepared reports to the JAZMP

Monthly verification of results and resolution of outstanding issues

Opportunities

- Effective reporting from back- clinical, pharmacy and other information systems
- Compliance with standards and global pharmacovigilance data files in human medicine (ICSR E2B R3, EMA, WHO)
- Connecting with eHealth solutions and the opportunity to provide ADR information in the patient's electronic health record
- An advanced solution in the EU

Architecture of planned IT solutions



Instructions for preparing XML

For developers (JAZMP):

- instructions for preparing a simple ICSR

JAZMP

Posredovanje podatkov
o neželenih učinkih zdravil (NUZ) s strani izvajalcev
zdravstvenih storitev

Verzija dokumenta: 0.02

Instruction to reporters of ADRs (JAZMP):

- for for healthcare professionals

Result (developers):
- test XML

Test r3 UR.xml

NAVODILO POROČEVALCEM

Navodila so namenjena tistim, ki bodo vnašali podatke v poročilo o NUZ in predstavljajo delovno navodilo za lažje razumevanje in izpolnjevanje posameznih polj v poročilu.

Zaradi nadaljnjega dela s poročili je zaželeno, da se v poročilo vpišejo vsi podatki, ki so znani. Več podatkov kot je vpisanih o neželenem učinku, terapiji... bolj kvalitetno je nadaljnje delo s poročilom. Zato prosimo, da se vpisuje čim več podatkov.

E2B 3R OZNAKA	NAZIV ELEMENTA (ANG/SLO)	NAVODILO POROČEVALCEM
C.1.1	Sender's (case) Safety Report Unique Identifier Številka poročila	Poročevalec tvori številko začetnega poročila kot je dogovorjeno z JAZMP . V primeru pošiljanja nadaljnjega poročila (follow up): - če zaledni sistem omogoča dopolnitev začetnega poročila (ki je bil že poslan na JAZMP), poročevalec uporabi to možnost: dopolni začetno poročilo z novimi podatki, pri opisu neželenega učinka zdravila (NUZ) pa navede, da gre za nadaljnje poročilo (FU1, FU2, FU3...) in ga nato z isto številko pošlje na JAZMP, - v primeru, da zaledni sistem ne-omogoča dopolnitve začetnega poročila, naj poročevalec tvori novo poročilo in pri opisu NUZ navede, da gre za dopolnitev že obstoječega poročila (FU1, FU2, FU3...).
C.1.2	Date of creation Datum kreiranja poročila	Poročevalec vpiše datum dneva, ko je izpolnil poročilo.
C.1.3	Type of Report Vrsta poročila	Poročevalec iz šifranta izbere za katero vrsto poročila gre. Pod oznako Poročilo iz študije, so mišljene samo ne-intervencijske študije; poročila o NUZ iz kliničnih študij se ne vnašajo preko tega sistema. Šifrant: 1 = spontano 2 = poročilo iz študije 3 = drugo 4 = ni znano