

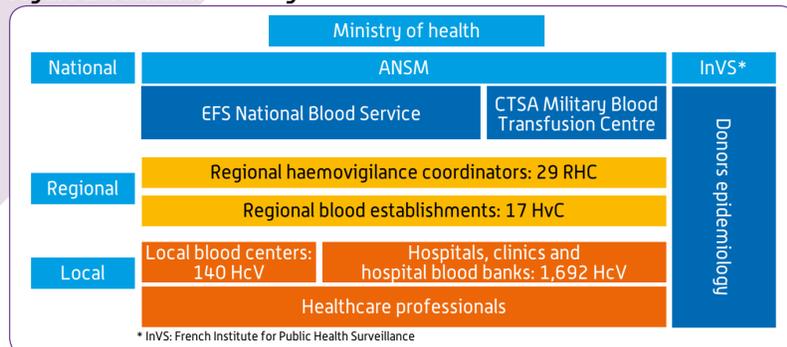
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## BACKGROUND

The French haemovigilance (HV) system is organised by the ANSM (former Afssaps), French Competent Authority for health products, in a network (Figure 1) integrating different levels: national (French national blood service (EFS), Army blood centre (CTSA)), regional (regional coordinators (RHC) and HV correspondents (HvC) of regional blood establishments) and local levels (HV correspondents (HvC) of hospitals and clinics and sites of blood establishments).

The epidemiological follow-up of blood donors is carried out by the French institute for public health surveillance (InVS).

**Figure 1. French haemovigilance network**

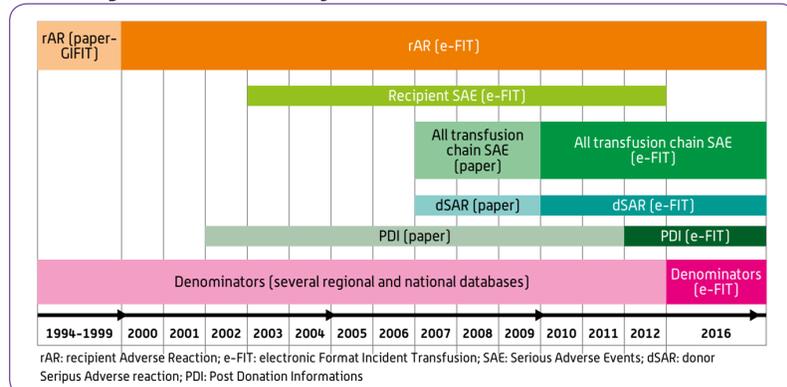


This system was set up (Figure 2) in 1994 to collect, supervise and evaluate all the adverse reactions occurring at the patients (rAR) and to collect denominators. The others notifications templates were added successively in 2002 for PDI, in 2003 for recipient SAEs, in 2007 for all transfusion chain SAE and dSAR.

From 1994 to 1998, reporting was made in paper form sent by fax. And in a 2nd time via the 1st generation of national HV database, called GIFIT.

In 2003, the ANSM has developed an IT system for reporting, called e-FIT to improve collection, supervision and evaluation of the HV reports. This system was available for the HV network in 2004.

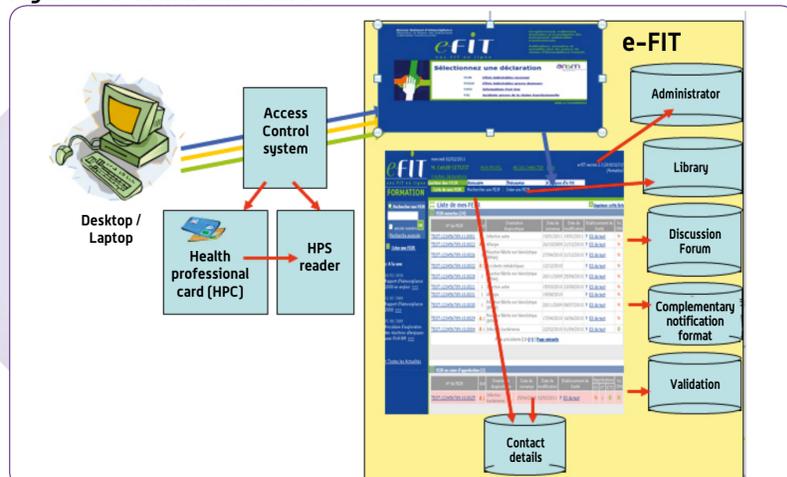
**Figure 2. Time table of the implementation of the French Haemovigilance in e-FIT IT system**



## WHAT IS E-FIT? HOW IT WORKS?

e-FIT is a secure IT system with access restricted to health care professionals (Figures 3, 4). Every user of the French HV network is registered by the e-FIT administrator via his personal details and his establishment (BE, hospital or clinic, regional health agencies, ANSM, EFS, CTSA). The access to the data is governed by the profiles of each member.

**Figure 3. e-FIT/Architecture**



**Figure 4. e-FIT homepage – access with HPC**



e-FIT reporting is based on 4 templates (donor's SAR, recipient's AR, SAE, and PDI). (Figure 5).

**Figure 5. e-FIT homepage – access to notification templates**



e-FIT allows real-time sharing of information between authorized members and thus a rapid analysis at each level, and implementation of corrective measures if needed, and it's a quick alert system for serious and rare reactions and events.

For each report initiated in the system by the local correspondent, the authorized individuals receive an e-mail message at the different steps of the procedure. The report file can be modified by the various professionals until the report is finally validated and locked.

In order to help the reporters, several guidelines were developed and are available on-line in e-FIT.

The annual data on blood collection and recipients are also collected, and this allows calculation of incidence rate events per 100,000 donations or blood components.

e-FIT database contains more than 165,000 reports. Among these, 77% are reports of rARs, 15% of dSARs, 5% of SAEs and 3% of PDIs.

## SUMMARY

The e-FIT system is continuously evolving to meet the needs of national and international users.

e-FIT allows real-time sharing of information and thus a rapid analysis and it's a quick alert system for serious and rare reactions and events.

It also serves to prepare the annual HV reports (national, European (EC, EDQM) and international (ISTARE, WHO)) and to participate to several surveys.

Authors are acknowledging all the members of the HV network for their continuous involvement and their prompt and efficient cooperation.