Dear Dr Arlet,

Prof Tony Frew passed your mail and our group, working under the aegis of the EAACI may be interested for some part.

I am in charge of the European network for drug allergy, a network of clinicians and researchers. Based on the success of this drug allergy network and the need to improve the awareness of drug allergy reactions in doctors, patients, scientists, health organizations and industries, the project WONDA has recently been proposed. This broder project, which represents a network of excellence of centres interested in drug allergy diagnosis, understanding and prediction, is enclosed. It has grown up progressively over the last months and many other scientific societies (toxicology, chemistry, pharmacovigilance) and SMEs involved in drug allergy prediction and diagnosis have endorsed the project.

Its ultimate goal to improve the awareness, diagnosis and prevention of these rather common diseases will have a beneficial effect on patients and allergy research and industry. Indeed, it will help industries to put safer drugs into the European market - drug allergy being the leading cause of drug withdrawal after commercialisation. It will also help diagnosis compagnies to launch drug allergy diagnosis and prediction tests.

WONDA is waiting for funding, but at the present stage, it has a special work package on pharmacovigilance (objectives below) and I am wondering whether this might be of interest for your project.

Waiting for your input,

Yours sincerely

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Optimizing pharmacovigilance system and declaration network (WP2-4).

Hypersensitivity drug reactions are but one of the many different types of adverse drug reactions. They may be potentially life-threatening, prolong hospitalization, affect drug prescribing patterns of physicians and result in socioeconomic costs. Although classified as type B unpredictable reactions, not all drugs have the same rate of hypersensitivity. In most countries adverse drug reactions are declared to local pharmacovigilance systems and are part of the postmarketing surveillance. This mostly rely on voluntary declaration by physicians, other health professionals and sometimes even self reporting of reactions. Under reporting is a problem constantly pointed out in most published studies even when life threatening reactions are concerned. Serious reactions or the most unusual are the ones more prone to be declared. Sometimes the reporting and process system is complex and it is not easily applied in every day practice. The use of probability scales to assess the relationship between an adverse drug reaction and therapy of a patient are frequently utilised by the National Committee on Safety of Medicine. Many of these methods use algorithms based on the patient's clinical history taken either prospectively or retrospectively by chart review. These methods combine several criteria: chronology and symptoms of the reaction and, in some cases, scientific literature. Therefore, the majority of declarations relies predominantly on the use of grades of suspicions (likelihood), and most of the reactions are not fully investigated. However, these methods carried out by pharmacologists are not designed to make definite decisions but rather to classify adverse drug reactions on the basis of the likelihood of a causal relationship between the drug and the reaction. Their use is essential for the filing of reports and for facilitating database analyses. In some countries an effort has been made in order to improve and complement the existing systems but mostly in specific conditions (anaesthetic reactions, anaphylaxis, hepatitis and bullous diseases).

The objectives of this WP is *(1)* to optimize already existing pharmacovigilance algorithm by using the specific drug allergy/hypersensitivity database of WP2-1 and the WONDA network of clinicians and *(2)* to ensure a continuous update and periodical review for possible alerts to National Committees on Safety of Medicine. The already existing declaration networks could indeed benefit from this collaborative project in terms of quantity (increased number of declarations) and quality (well documented cases, improved algorithms). On line optimized declaration should be developed. It is important to keep in mind that declaration procedures and networks should be as simple as possible, easily accessible and online. The optimization of the existing systems and collaborative work with this new network would be very helpful for drug safety organizations, for pharmaceutical companies (post marketing) and should allow the implementation of better protective measures for patients.

The model of the British Health Care system records could be used as a starting point. With a drug allergy/hypersensitivity database in place linked to a searchable comprehensive electronic medical record clinical risk factors could be studied.