**Vid Stanulovic, MD**

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**Biosketch**

Dr Vid Stanulovic obtained his medical degree, followed by clinical specialization and master degree in clinical pharmacology from the Faculty of Medicine in Novi Sad, Serbia. His second masters in clinical research (développement clinique des produits de santé) was awarded by Claude Bernard University in Lyon, France. His PhD thesis on the topic of safety of biopharmaceuticals was awarded the Semmelweis University in Budapest, Hungary.

Dr Stanulovic lectured and published internationally focusing on pharmacovigilance, clinical pharmacology and clinical research. He is author/co-author of over 30 scientific papers and book chapters. He is a guest lecturer at under and post-graduate programs of medical universities in Belgrade, Serbia and Budapest, Hungary.

His career is devoted to drug development and safety in several pharmaceutical research organizations and pharmaceutical companies.

**Abstract: Maybe It's Not (Primum non nocere et optimum curare)**

While the basic prerequisite of "primum non nocere" is true, in complex clinical situations of high medical need and no other proven therapies, withholding effective therapies unnecessarily is also harmful. Continuation of treatment may be justified despite the risk of adverse drug reactions in selected cases of proven need of the suspect (or causative) drug, Hepatic ADRs have few specific characteristics to be monitored or assessed in intentional rechallenge. Liver enzyme profiles are useful for monitoring of direct hepatotoxic or cholestatic damage. Specific clinical features of systemic hypersensitivity may identify high-risk reactions. Pharmacogenetic predictors should always be considered. But more often than not, standard clinical precautions in benefit/risk optimization should suffice.
Benefit/risk balance of suspect drug should be evaluated with respect to the benefit/risk balance of the best alternative treatment or no treatment - keeping in mind that the risk of rechallenge may be either higher upon rechallenge (e.g. in case of immune sensitization) or lower if appropriate risk minimization measures have been taken.
If intentional rechallenge is to be performed, it must be based on a structured yet flexible plan of action tailored to each drug-adverse drug reaction combination. Such a plan would serve a dual purpose: as a basis for explaining an individual physician's or investigator's action to any concerned party (including ethics committee/review board), and as a practical guide for the clinician and their team.