Safety of vaccine adjuvants: Focus on autoimmunity workshop report

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Questions are often raised about the safety of vaccine adjuvants, particularly in relation to autoimmunity or autoimmune disease(s)/disorder(s) (AID). The International Life Sciences Institute (ILSI) Health and Environmental Sciences Institute (HESI) formed a scientific committee, which included technical experts from academia, government regulatory agencies and industry to consider adjuvant safety and conducted a wide literature review and a two-day workshop. This large topic was broken into subtopics and focused on oil-in-water emulsions and Toll-like Receptor (TLR) agonists adjuvants, use of animal models and biomarkers for the evaluation and prediction of AID and addressed key issues including: the value of animal models of autoimmunity for studying novel vaccine adjuvants; whether there is scientific evidence indicating an intrinsic risk of autoimmunity with adjuvants, or a higher risk resulting from the mechanism of action; and if there is compelling clinical data linking adjuvants and AID. The tripartite group of experts concluded that there is no compelling evidence supporting the association of vaccine adjuvants with autoimmunity signals. Additionally, it recommended that if future research focused on the potential effects of adjuvanted vaccines on AID, it should consider carefully the experimental design in animal models particularly if they are to be used in any risk assessment, as depending on the study design, the results could be misleading. In addition, studies on the mechanistic aspects and potential biomarkers related to adjuvants and autoimmunity phenomena could be developed.