IDEA
International Dialogue for the Evaluation of Allergens

Key conclusions from the Working Group meeting on the

Feasibility of a study to assess the effectiveness of QRA

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- The WG reaffirmed the need for clinical assessment of the performance of QRA2.
- The surveillance system alone may not verify whether the QRA2 is effective due to confounding factors.
- Despite the confounding factors, diagnostic patch testing of dermatology clinic patients (surveillance system) was seen as a critical pillar in the long term evaluation of QRA.
- Choice of materials for this surveillance system should include new materials beyond FM-1, FM-2 and the 26 allergens labelled on cosmetic products in Europe. The WG suggested about 5 new materials, which ideally should be part of the 2012 SCCS list, be relatively stronger sensitizers, preferably synthetic (to avoid cross reaction with naturals), be used in relatively high volume, and in product types leading to high consumer exposure.
- The IDEA Management Team is tasked to follow up on the development of a protocol for the surveillance system including a list of materials for approval by the working group.
- The WG is supportive of clinical work complementary to the surveillance system, favouring establishment of an approach which would minimize confounding factors (i.e. prospective study).
- The favoured design for such prospective study would involve 3 cohorts (unexposed, "safe" exposure, "sensitizing" exposure) and use a potent sensitizer to keep group sizes manageable. For ethical reasons, such a sensitizer would not have any real-world relevance.
- Given a number of open protocol questions, the working group proposed a pilot study. A protocol for such a pilot study will be developed by the group of interested volunteers from the IDEA working group.

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