IDEA

Surveillance system

Status update

IDEA WG Meeting

Waterloo

December 7, 2017

Surveillance System

- Developed in consultation with and involvement of:
  - 2 IDEA workshops on strategy and protocol design
  - Initial draft protocol proposal:
    - Ian White (St Johns Hospital)
    - Jeanne Duus Johansen (Gentofte hospital)
    - Wolfgang Uter (University of Erlangen)
  - Data management and protocol design:
    - Wolfgang Uter (University of Erlangen)
  - Quality control and patch test preparation:
    - Magnus Bruze, Marlene Isakson (University Hospital Malmö)
    - Bo Niklasson (Chemotechnique)
  - Subgroup of industry stakeholders:
    - Refinement of the approach including preliminary material proposal and budget outline

Surveillance System

Key Criteria

The Surveillance System must:

- Be **relevant** by implementing & delivering post-market monitoring
- Be **meaningful** to the stakeholders by providing additional information and insights related to clinical reactions not possible with the current ingredient list
- Collect **material-specific data,** to assist investigation of cases of increases in and/or reduction in allergy (e.g. with regard to other relevant exposures)
- Be **embedded in and linked** with the entire IDEA project (Holistic approach)
- Allow for **feedback** of the data into the IDEA project for consideration of appropriate actions
- Have scientific publications of the outcome.

Surveillance – Key Parameters

- Number of patients per cycle
- Number of years (Cycles)
- Publication of study protocol
- Source and cost of preparing new patch test materials/delivery systems
- Recruitment of sites (clinics)
- Study development, training, monitoring and project management
- Statistical analysis plan
- Hosting of data management
- Analyses, reporting and interim and final publications

Surveillance Project

Key Project Elements

- Patch Test Materials:
  - Materials already routinely tested by the dermatologists
  - 5 fragrance ingredients not previously generally available to the dermatologists
- Start with a **pilot** study (3 sites) designed to:
  - Critically assess and address operational aspects before rolling out the broader project
  - Prepare for material selection and patch test concentrations determination, develop and publish protocols and statistical analysis plan, run protocol operational test
- Establish the **hypothesis** based on the expectations from this study on each ingredient
- **Clear objectives** and **success criteria**, transparently defined and communicated well in advance

Criteria for Selecting NEW Ingredients

- Project focus on demonstrating responsible care allows a range of materials to be identified
- Practical physical considerations allow for inclusion of either 5 or 10 new materials
  - Initially focus on 5
- Proposal worked out by an industry group (suppliers and consumer product manufacturers):
- Criteria
  - Ideally part of the 2012 SCCS list (most preferable listed in Tables 13.1, 13.2 and 13.3), and/or the European Commission proposal for consumer information published in 2013 and/or having or receiving an IFRA Standard
  - Variety of potencies
  - Synthetic (to avoid cross reaction with naturals)
  - Used in relatively high volume and in product types leading to high consumer exposure
  - Consider 'other uses'

Lists of candidate materials

Materials suggested and the respective rationale are summarized in a separate table.

Surveillance Project – Implementation Details

- Includes 30 standard materials (FM1, FM2, 26 allergens [omit some of infrequent sensitisers?], oxidized linalool and limonene and 5 new
- Agree and do range-finding test on new materials (5)
- Use calibrated syringe dosing system for all materials
- Develop and offer quality training and support to participating sites
- Pilot involving 3 sites (6 months, 100 patients per site), building on range-finding, designed to critically assess and address operational aspects – financing ensured by IFRA Board
- Payment to ESSCA to support work data collection/analysis etc.
- After pilot, assume average number of sites is 30 over subsequent cycles at 300 patients per site (9,000 per cycle)
- No payments to clinics

Surveillance Project

Benefits

- Ensure industry as a whole is engaged in a responsible stewardship program by fulfilling a commitment made under IDEA
- Provide diagnostic support
- Strengthen dataset on routine patch test materials and provide baseline for new materials
- Provide additional information and insights related to clinical reactions
- Provide feedback to IDEA project

THANK YOU