

SOP for Common Commentary

- **Purpose**
 - Provide informal, non-binding comments to sponsors on pediatric development plans that have been submitted to both FDA and EMA, which are under review by both Agencies and have been discussed at the Pediatric Cluster.
- **Scope**
 - Product-specific
 - Serious or life-threatening disease, particularly those with few or no therapeutic options (e.g. oncology product)
 - Non-life threatening disease but major issue (e.g. trial design, endpoint, dosing or safety concerns)
 - General approach to study a disease (e.g. Gaucher disease)

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- **Process**

- **FDA or EMA nominate a product or specific topic**
 - **PIP submitted to EMA and PSP and/or PPSR to FDA**
 - **Preferably early in the regulatory process (i.e. Day 60 PDCO discussion or earlier and iPSP under review)**
- **Issues identified for discussion**
- **Both Agencies agree to the proposal**
- **Pediatric Cluster is the forum for the discussion**
- **One or more discussions may be needed**
- **FDA and EMA alternate in drafting the discussion summary, identifying similarities and differences in approach**
- **Document cleared by both Agencies is sent to the sponsor**
- **Comments are **NOT** binding- they are **NOT** regulatory advice**