



REGISTRY ANALYSIS CONCEPT SHEET

Concept Sheet ID and Document Name: *CS_REG_YYYYMMDD_Identifier*

Please provide the following information to the best of your knowledge when submitting a request for Registry data. Upon receipt of your draft Concept Sheet, we will contact you to discuss the objectives and an Analysis Plan.

SECTION 1: CONTACT INFORMATION	
Date of Request	
Requester Name	
Email	
Phone	
Affiliation	
Additional Requesters	<i>If your request is on behalf of another individual please add their name and affiliation here</i>

SECTION 2: TITLE AND AUDIENCE FOR DATA REQUEST	
Topic/Title for Request	
Target Audience	<i>Abstract, manuscript, oral presentation, payor/reimbursement report, site information, or other purpose. Please specify relevant dates, venue, target journal, etc. where applicable.</i>

Questions and completed forms can be directed to
Imad Al-Dakkak, Associate Director, Epidemiology: Imad.Al-Dakkak@alexion.com



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SECTION 3: ANALYSIS PLAN	
Background / Literature Review	<i>Provide background or list relevant literature or references related to your proposal.</i>
Objective(s)	<i>E.g. To determine if eculizumab lowers serum creatinine in treated patients, as compared with untreated patients.</i>
Hypothesis	
Patient Population	<i>Specify any known inclusion, exclusion criteria, and any subgroups of interest or for comparison (e.g. pediatrics and adults, or patients with and without transplant, etc.):</i>
Data Elements	<i>E.g. list the specific lab values, diagnostic history information, symptoms, concomitant medications, patient-reported outcomes, etc. of interest. Include specific definitions or categories, where known.</i>
Time Points	<i>E.g., time of aHUS diagnosis, time of Registry enrollment, period of enrollment through six month follow-up, etc.</i>
Methodology (if known)	<i>E.g., descriptive analysis, change from baseline to last follow-up, adjusted comparison of time to event between sub-populations, etc.</i>

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