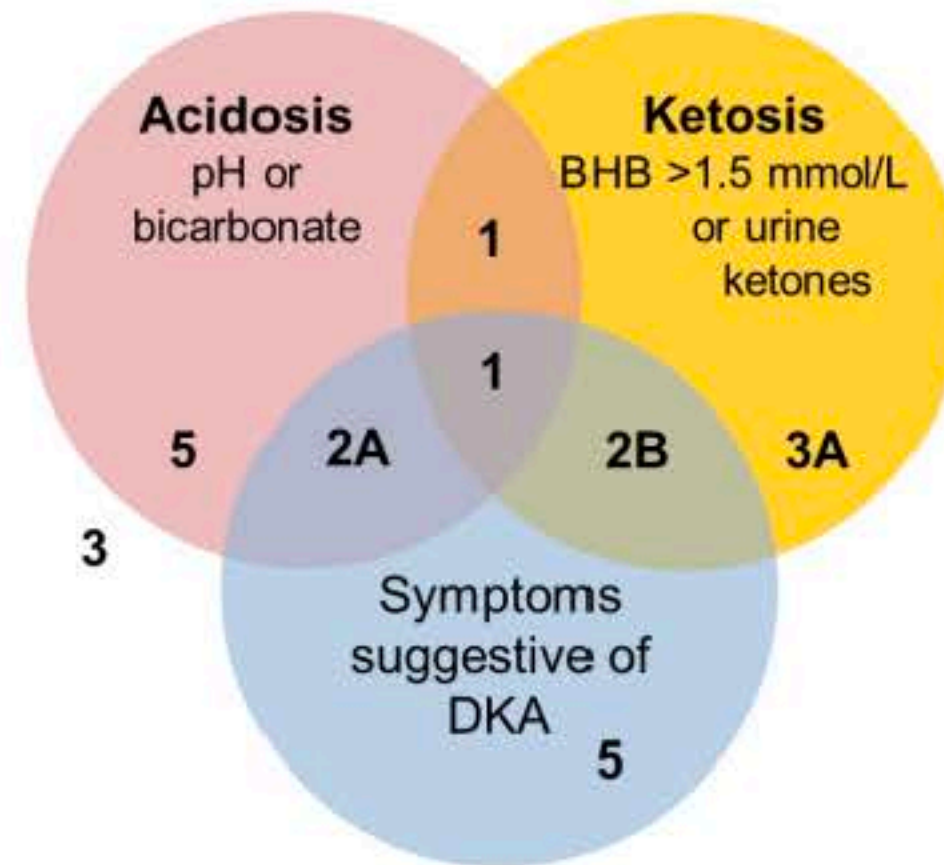


Trigger events for adjudication

1. All investigator-reported DKA events and selected investigator-reported terms indicative of DKA
2. All BHB readings (including e-diary data) >1.5 and <3.8 mmol/L and selected terms indicative of acetonemia plus
 - Reported symptoms suggestive of ketoacidosis, or
 - Accompanied by reports of hospitalization, or
 - Reported as a serious adverse event
3. Any BHB reading ≥ 3.8 mmol/L

Parameters for adjudication



Case definitions for ketoacidosis adjudication were provided as guidance; final decision on case category based on adjudication committee judgment

Case definitions

1. **Certain ketoacidosis:**
 - Confirmed ketosis plus confirmed acidosis (with or without symptoms)
2. **Potential ketoacidosis:**
 - A. Confirmed acidosis plus symptoms suggestive of DKA
 - B. Confirmed ketosis plus symptoms suggestive of DKA*
3. **Unlikely ketoacidosis:**
 - Evidence of absence of acidosis without ketosis
 - A. Unlikely ketoacidosis but ketosis:**
 - High ketones without acidosis and without symptoms
4. **Unclassifiable:**
 - Acidosis or symptoms only