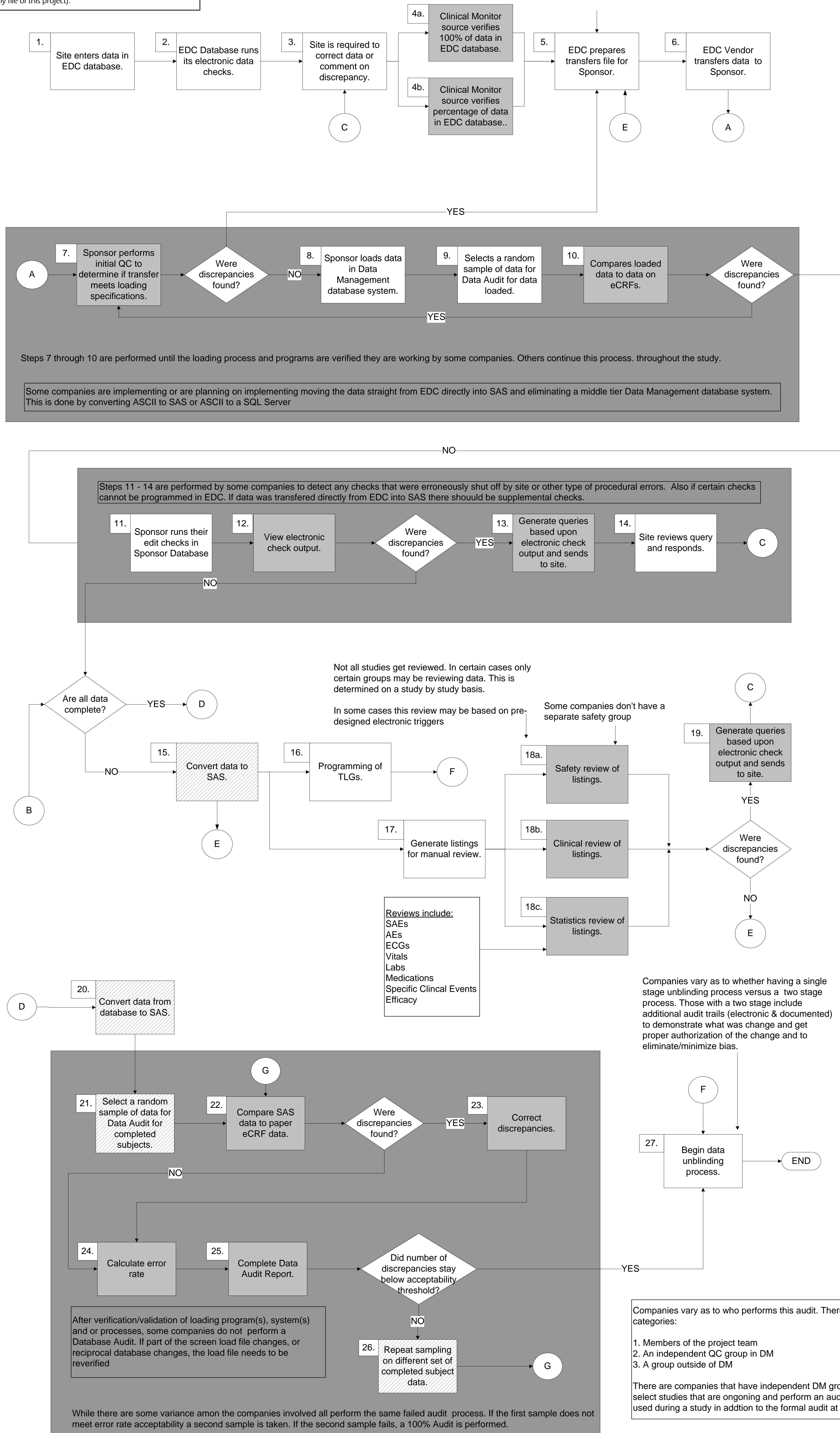


**Review Instructions**

- Does the flow reflect your process, and if not, how does yours differ?
- Are the flows easy to follow? If not, how could they be improved?
- What are your thoughts on the value of each step as outlined, and why should it be included or dropped? If it depends upon whether other steps are performed, please define them.
- To your knowledge, has the value or contribution to data accuracy of any of these steps been quantified, and if so, can you send us the information and/or the reference? (Note: some are listed in the bibliography file of this project).

# EDC Entry

Data Transfer plans are designed and approved prior to 1st transfer.



**Shaded group of steps represents variance among participating companies**

**In certain steps a letter follows the number to help demonstrate a variance in the process as used by different companies.**

**Shade boxes represent manual QC processes**      **Patterned boxes represent certain companies or processes use a manual step while others are automated**