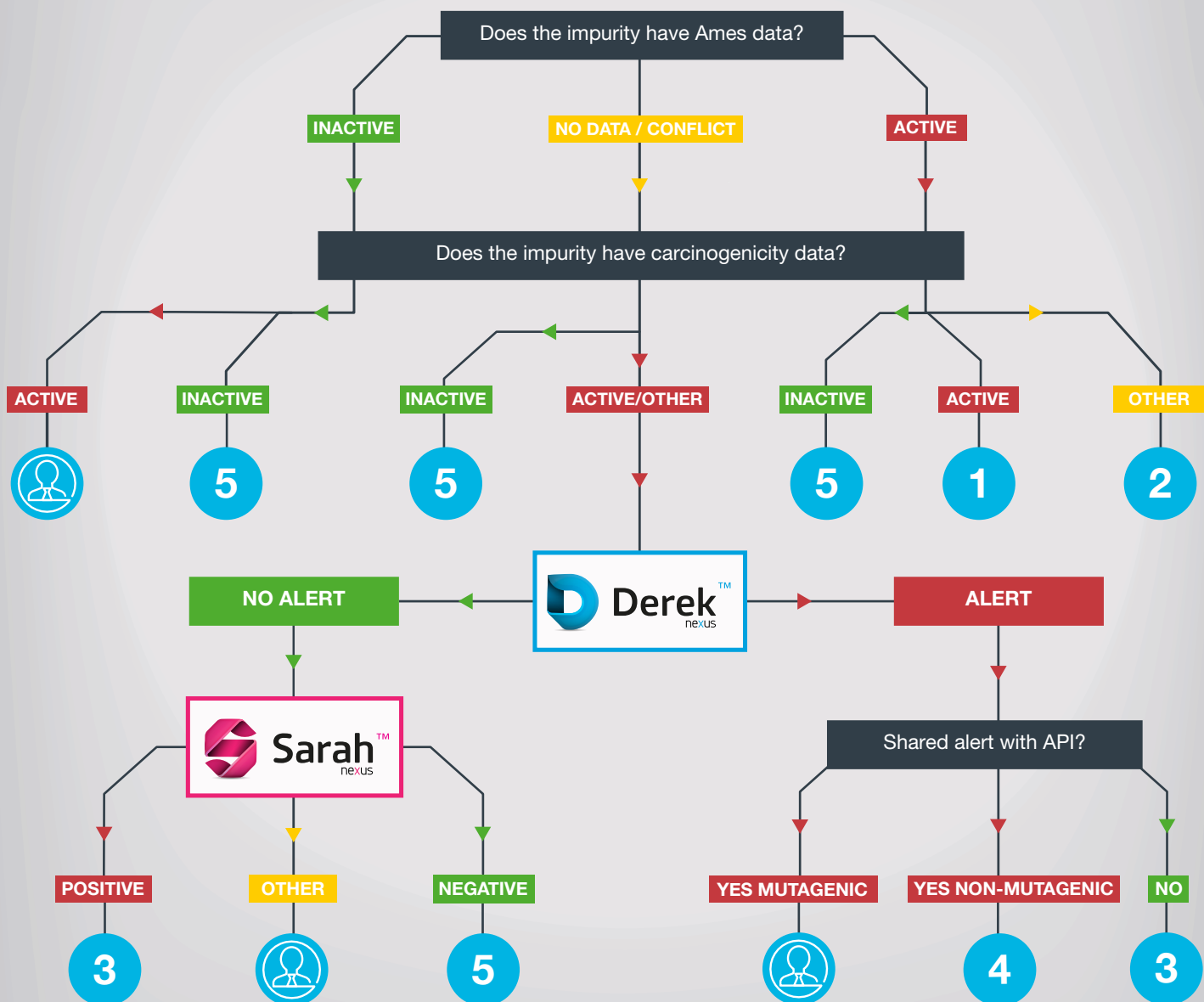


An Automated ICH M7 Classification Workflow

Assisting expert assessment and regulatory submission

A classification workflow tool has been developed by Lhasa Limited to aid in the submission of impurities under the ICH M7 guideline¹. The workflow uses two *in silico* tools, Derek and Sarah Nexus, alongside experimental Ames and carcinogenicity data to predict an ICH M7 class. This workflow tool presents the classifications in a submission ready format, while still allowing the user to supplement the workflow with their own data.

The workflow is described below and shows how impurities are classified.



Sources of Data:


- **Ames Data:** The Summary Call table within Vitic Nexus
- **Carcinogenicity Data:** The Lhasa Carcinogenicity Database

To find out more about the ICH M7 guideline and how Lhasa Limited can offer solutions, visit our website: www.lhasalimited.org/ich-m7.htm

References

1. ICH HARMONISED TRIPARTITE GUIDELINE, http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Multidisciplinary/M7/M7_Step_4.pdf

Key

These impurities require further, expert assessment 
ICH M7 class 