The edge of lesion

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Summary

At AstraZeneca we utilise a wide variety of flank tumour models in rodents to gather data on the effectiveness of our Oncology drugs. During these studies tumour condition is closely monitored for appearance of lesions; typically a change of shape or appearance of the tumours, including scabs, holes or areas of necrosis; that will lead to humane endpoints as outlined by specific criteria in the project licence (PPL) (Figure 1).

However we identified an opportunity to refine our use of flank tumour models in rodents by developing a tumour risk classification scoring system. This system intends to simplify and standardise the decision-making process for personal licence holders (PILs) working across all our models; act as a training aid for new PILs; and support our responsibility to minimise pain, suffering, distress or lasting harm under ASPA.

Results

We have developed a tumour lesion classification scoring system that includes three risk categories (Figure 2):

- Low risk: Tumours that are growing as expected with no concerns, including small dry lesions. Standard daily examinations can continue.
- Medium risk: Tumours with borderline or difficult to characterise lesions, including sunken, dark or partially open lesions. An additional daily examination may be necessary.
- High risk: These include tumours that are weeping, bleeding or holed. The animals that have reached this point should be humanely killed.

As tumours grow, lesions may pass through all three of these risk categories; or they may remain in the low or medium risk category until the study ends. This depends on the individual nature of the cell line or additional factors such as treatment effect.

Figure 1. Lesions.

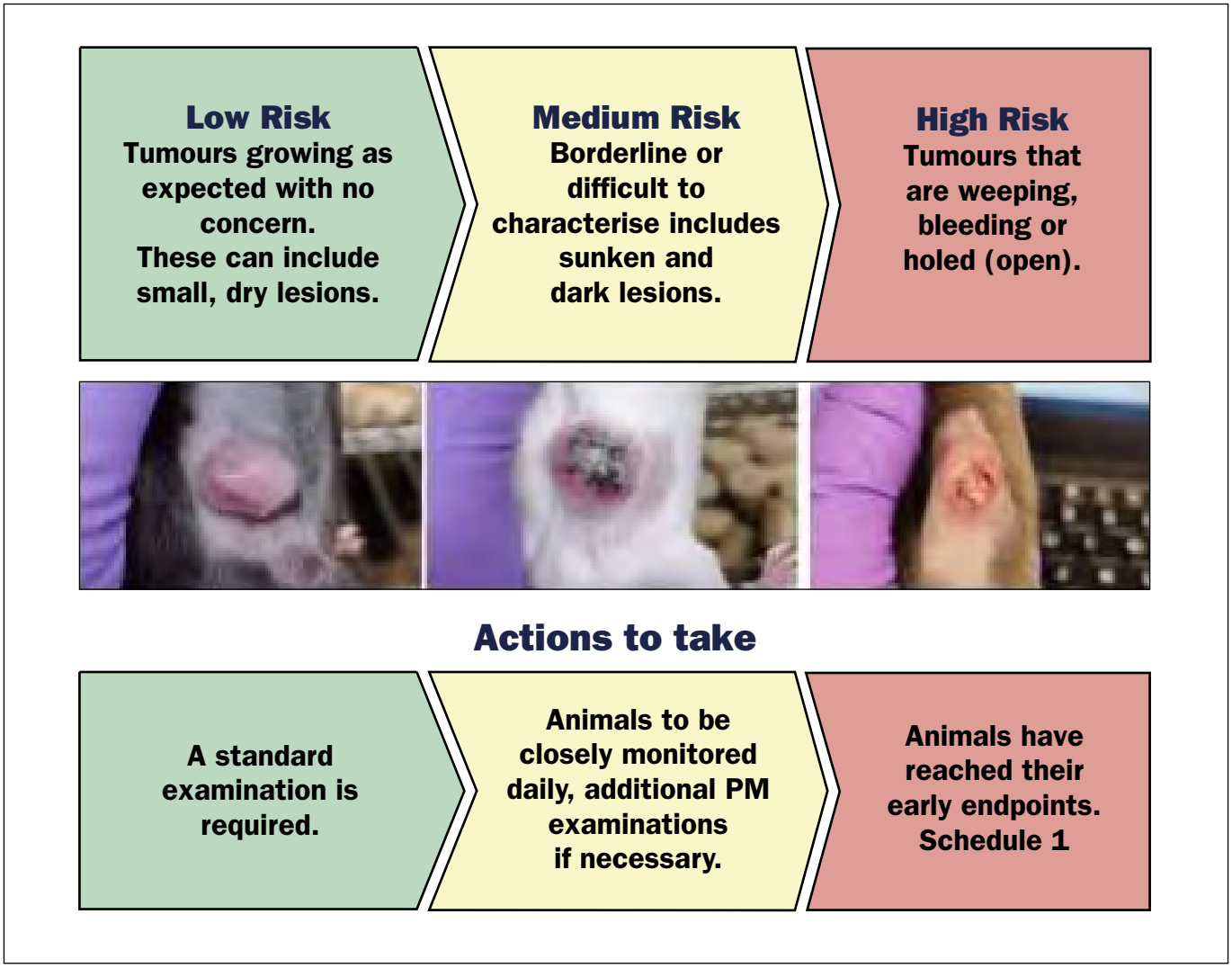

Figure 2. Risk categories.

Conclusions

- We have produced a tumour classification scoring system which is applicable across our many flank tumour models to enable consistent assessment for all *in vivo* scientists.
- We collected data (including images) across multiple cell lines at various stages of risk classification. This information will be displayed in the holding and procedure rooms to aid reporting and decision making.
- We provided specific instructions on cell lines that have defined humane endpoints in the PPL including the cell lines LL2, B16F10, MC38, and 4T1, which ensures compliance and the highest level of Animal Welfare.