Fast-tracking the development of efficacy and toxicity data for registration of phytonematicides

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Introduction

Worldwide, the major obstacle in generating preclinical data for registration of phytonematicides is lack of standardised procedures. The registration authorities hardly prescribe the "do-it-yourself" procedures.

Materials and methods

Using the Curve-fitting Allelochemical Response Dose (CARD) algorithm computer model, we developed a six-step model for the provision of preclinical data that are compliant with "scientific merit" (experimental designs) and "fit-for-purpose" (regulatory tests) attributes in order to fast-track the development of standardised procedures in preclinical registration of botanical drugs using cucurbitacins as lead chemical compounds for both phytonematicides and botanical drugs.

Results

The six steps are summarized in Fig. 1. In addition to various regulatory tests, the innovators should familiarize themselves with terminologies used by registration authorities (*e.g*. concentration, dose, dosage, fit-for-purpose, pharmakokinitic tests, scientific merit, shelf-life, toxicity, *etc*). Initially, it is prudent that innovators work directly with the office of the registration authority or seek professional assistance.

Conclusion

CARD model provides all information required for registration of phytonematicides**.**

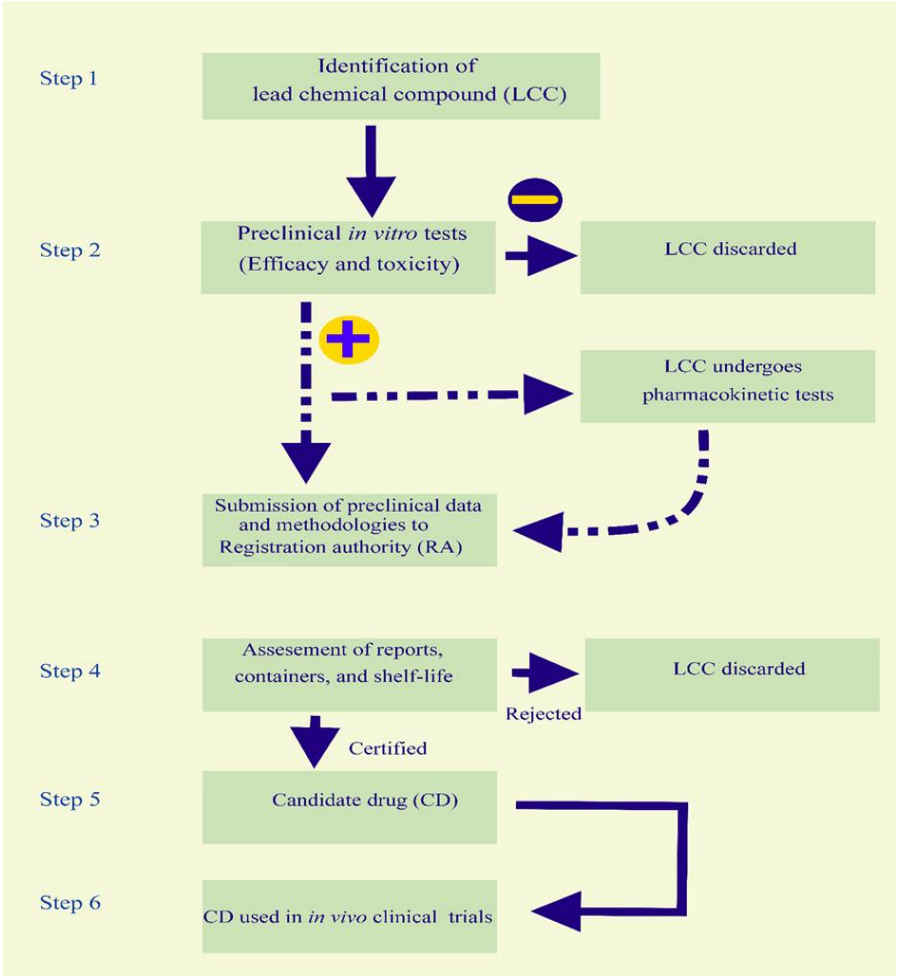

Fig. 1. Six step model in the registration of phytonematicides (botanical drugs).