

Cooperation within The Framework Of International Validation Studies

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The many and varied contributions of ZEBET towards the validation of non-animal methods are essentially unparalleled by any other organization. Almost since the inception of ZEBET in 1989, this group has taken a leadership role in designing, funding, conducting, analyzing and publicizing studies which show the usefulness of non-animal methods in making safety decisions. These contributions are well known to my organization - the Institute for In Vitro Sciences, Inc. (IIVS) – since over the years IIVS staff and ZEBET have been involved in many of the same validation activities. Nearly 20 years ago we first worked together on a large and costly eye irritation validation study co-sponsored by the European Commission and the British Home Office. Although the assays our laboratories personally conducted performed well, none of the methods in the study could be considered validated. In the face of this possible major set-back, ZEBET, IIVS and ECVAM worked together to propose a prevalidation approach that defined relatively inexpensive incremental steps which should be performed to make the validation process more efficient and cost-effective. Since then our approach has been adopted internationally for many successful validation efforts. Such successful ZEBET/IIVS collaborations have continued over the years, due to the fact that both organizations have strong, practical laboratory expertise which is used to ground validation programs in the realities of real life application of the assays. At the start of a study both ZEBET and IIVS share their scientific knowledge (often involving highly detailed Standard Operating Procedures) with all participating laboratories to ensure that the technical aspects are virtually guaranteed to be successful. ZEBET then follows up at the conclusion of the study by effectively communicating the results - in a scientifically credible way - to appropriate sections of the regulatory and political community. ZEBET's other strength is that they are inclusive of many different organizations, reaching out unhesitatingly to friends around the globe to forge an effective assemblage to promote the scientifically valid use of alternatives. This strategy, embraced by both ZEBET and IIVS, has resulted in numerous advances for the alternatives community, and we can only hope that ZEBET's effectiveness can last through several more 20-year periods.