Thank you for your work to standardize clinical trial summary information from manufacturers. This is an area that patient groups are keenly interested in.

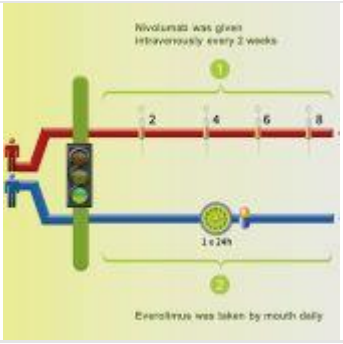
On behalf of the International Kidney Cancer Coalition based in Amsterdam (ikcc.org), I am writing to share our work in this area and offer commentary.

1. Infographics. We have piloted an infographic approach to help patients understand the design of a clinical trial, along with the top-line results. For an example, see here: http://www.10forio.info/clinical-trials/results-checkmate-025/infographic-study-results-checkmate-025

Based upon this work, we can see the need for some standard graphics and some common visual representations of results. Ideally the manufacturer responsible for the trial would:
a) produce the trial design schematic in an understandable/common format
b) complete the results infographic using the common format/ common graphical language

2. Our written summary is presented in a standard format answering the basic questions of Who/What/Where and is peer reviewed by medical experts and patient representatives to ensure objectivity (vs directly from a manufacturer) and usability.

Results Checkmate 025



Results Checkmate 025

Study of Nivolumab versus Everolimus in Pre-Treated Advanced or Metastatic Clear-cell Renal Cell Carcinoma - checkmate 025

View on **www.10forio.info** Preview by Yahoo

Based upon our experience to date we would strongly recommend the inclusion of patient advocates, medical writers, graphic designers, and plain language experts. Statements 81-85 in your Draft Consultation will need to be significantly stronger if the results are to meet the needs of patients.

"Consider involving patients, patient representatives, or advocates in the development and review of the summary information to ensure that it truly meets their needs. This won't be feasible for some studies but where it is a possibility, it may enhance the final version. Medical writers with experience of writing in plain language for the public may also be helpful."

We hope these comments are useful to your work.

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ikcc.org

Clinical trials website: www.10forIO.org
Social media: @ioKidney