Recommendations for improving the quality of reporting clinical electrochemotherapy studies based on qualitative systematic review

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CHECKLIST

Recommendations and minimal requirements for reporting clinical trial results on electrochemotherapy (key elements)

Trial design:

- ☐ Explanation of the rationale of the study
- ☐ Description of trial design and sponsorship
- ☐ Indication of trial endpoints
- ☐ Indication of inclusion and exclusion criteria
- ☐ Trial approval and registration
- ☐ Informed consent statement

Patient population:

- ☐ Patient demographic data (in tabular form)
- ☐ Setting - palliative or curative
- ☐ Tumor histology
- ☐ Disease stage (lymph node or visceral metastases)
- ☐ Description of target lesions treated with electrochemotherapy (anatomical location, number and size)
- ☐ Previous local treatments
- ☐ Concomitant oncological treatment
- ☐ Adjuvant and / or following oncological treatments

Treatment information:

- ☐ Indication of electroporation protocol (adherence to SOP or other)
- ☐ Type of anesthesia
- ☐ Drug (producer)
- ☐ Drug details (dose, concentration, route of administartion)
- ☐ Time interval between drug administration and application of electric pulses
- ☐ Technical details of the electric pulse generator, including type, manufacturer and version of software, if applicable
- ☐ Information about the electrodes used, for respective tumor(s)
- ☐ Number of electric pulses application per tumor
- ☐ Inclusion of a report on electrical parameters (n, T, U, I, f)*
- ☐ Adequacy of tumor treatment (treatment application success rate)
- ☐ Extent of the safety margins treated
- ☐ Number of treatment sessions (with interval between sessions)

* Legend: n = number; T = duration of pulses; U = voltage amplitude applied; I = current measured; f = pulse repetition frequency

Treatment outcome assessment:

- ☐ Time of response assessment
- ☐ Standardized response evaluation criteria (*e.g.* WHO, RECIST1.1, mRECIST)
- ☐ Time to local and systemic disease progression
- ☐ Standardized toxicity criteria (*e.g.* CTCAE v4.0)
- ☐ Quality of Life (QoL), patient reported outcomes (PRO)
- ☐ Track of patients lost to follow-up

Analysis and interpretation of results:

- ☐ Summary of trial endpoints
- ☐ Additional outcome parameters (*e.g.*, QoL, PRO)
- ☐ Predictive factors
- ☐ Results interpretation
- ☐ Future research directions