**Submission Themes:**

1. **Pilot Studies, P1**
2. **Validation Studies, P2**
3. **Reviews of Case reports/series, P3**
4. **Special Interest Topics, P4**

**Pilot Studies:** A small scale study aimed at exploring the potential and possible optimizations for a larger scale study. The exact size or “n” involved in a project that makes it a pilot versus a full study has never been defined. Although pilot studies are not intended for future case studies, a case report can, in principle, be the absolute minimum “n” of a pilot study. Thus, for the purposes of this journal the “n” for a clinical pilot study will range from 1 to ~100. A unique aspect of this journal is that large or full scale studies will be deferred to other sources of publication. This can only be determined through the review process, the “n” of 1 to ~100 is a soft range and will not be used to reject an article out right.

The use of the term: “statistically significant” will be reserved for a p<0.05 with a confidence level of 95%. For pilot studies only the expression of “possible statistical significance” will be allowed for a p<0.08 - >0.05 provided that an explanation on how further optimization and addressing confounders may aid a future study is offered.

General themes of Pilot Studies:

1. Case report
2. Case series
3. Small scale retrospective, cross-sectional, prospective, case-control, randomized control, surveys, and questionnaires
4. Animal research
5. *In vitro* studies

Should your manuscript be deemed by reviewers to be more than a pilot study one of two things will occur.

1. Rejection with permission to submit elsewhere, along with a letter of endorsement based on our reviewers comment to any journal of your choice.
2. Rejection with permission to submit elsewhere, but without a letter of endorsement.

Any submission under category 1 will be allowed to resubmit after at least 3 journal denials for consideration to publish in the special interest topic heading. This is done to ensure academic and scholarly work has an equal and fair chance to be published. Official comments from denials will be requested and reviewed.

**Validation Studies:** If studies start with a pilot project, then inevitably they end when it is validated. It is further important that validation occurs both internally and eventually externally. Here submissions of external validation of an unaffiliated researcher(s) work are welcome. Validation of expert opinion in practice parameters and/or guidelines are also welcome. Validating or repudiation of pilot studies will not be accepted as they are by nature initial studies intended for further optimization.

1. Validation or repudiation studies of an entire piece of work should be conducted with the same methods. Any deviations made beyond nominal differences must be explained and rationalized. Variance of findings are expected, but will still be considered validated so long as the overall conclusions of the studies remain in agreement. The degree of validation or repudiation is outlined below. The scale is applicable to the individual parts and whole of the studying undergoing validation.
2. Validation or repudiation of part of a study only will also be considered. However the author will have to provide clear explanation of why only part of a study was repeated and why only a portion of the whole study warrants reporting.
3. Validation or repudiation of aspects of expert advice and/or practice parameters, guidelines will also be accepted. The scale will not apply in these manuscripts.

**Validation and Repudiation Scale:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Validation** | **1** | **2** | **3** | **4** | **5** |
| % reproducible | 95-100% | <95, >85% | <85, >75% | <75, >65% | <65, >50% |
|  |  |  |  |  |  |
| **Repudiation\*** | **1** | **2** | **3** | **4** | **5** |
| % reproducible | <50, >45% | <45, >35% | <35, >25 | <25, >15% | <15% |
|  |  |  |  |  |  |

\*Repudiation is not an indication or statement of fraud or research misconduct.

**Reviews of Case reports/series:** Many discoveries start as case reports/series however they are rarely compiled with similar cases and reviewed. As a result case reports and series are hardly ever validated even if other cases are known. This presents the potential perception that unique reported cases are rarer then they truly are. Mechanistically connected reports are also difficult to discern in the literature for the potential of generating new ideas and fresh perspectives owning to their isolated nature. It is for these reasons that reviews of compiled case reports and series centered on a common theme will be accepted.

1. Validation of case reports/series are not accepted as stand alone submissions. They will, however, be allowed to be added to a review of case reports/series by the submitting authors.

**Special Interest Topics:** To help increase diversity of topic exposure for our readers one article per issue will be allowed that does not fit any of the topic headings above. They may be in the form of a:

1. Letter to the editor
2. Medical Hypothesis
3. Perspective or opinion
4. Medical or health policy position
5. Large scale or full original contributions previously endorsed through the pilot study review process