|  |  |
| --- | --- |
| **Scoring Criteria** | **Score** |
| 1. Phase |   |
| 2. Number of Participants |   |
| 3. Number of Trial Arms |   |
| 4. Number of IMPs |   |
| 5. Type of Study |   |
| 6. Vulnerable Groups |   |
| 7. No of organisations/departments involved |   |
| 8. Design |   |
| 9. Study Team and their experience |   |
| 10. Number of sites |   |
| 11. Length of study |   |
| 12. Complexity |   |
| **RGIT Monitoring Risk Score** |  |
| **RGIT Monitoring Risk Level** | **Low/****Similar to usual care/****Substantial /****High (Delete as applicable)** |

**Monitoring Risk Assessment**

**Risk Assessment Scoring**

The RGIT monitor should use the following scoring to determine the frequency of monitoring visits for a Clinical trial of Investigational Medicinal Products (CTIMP) study.

Please note that any CTIMP study where the investigated medicinal products (IMPs) are **First in Mankind,** these should automatically be considered as “high risk” .

**Phase.**

This question refers to what phase the study is. The earlier the phase of study, the less information we may have about the IMP and therefore the greater the potential for unexpected adverse events. These should be scored as follows:

Phase 1 4

Score

Phase 2 3

Phase 3 2

Phase 4 1

**Number of participants**

This question refers to the number of participants in the study. The greater the number of patients, the more potential there is for deviations from the study protocol or study processes and for things to be done in error:

1-10 1

Score

11-50 2

50-100 3

101+ 4

**Number of Trial Arms**

This question refers to the number of arms in the study. There is greater potential for errors to be made in terms of IMP allocation if there is a larger number of arms in the study:

0-2 1

Score

3-4 2

5+ 3

**Number of IMPs**

This question refers to the number of IMPs. If there are placebos in the study, these should also be included for this question. This question should be scored as follows:

0-2 1

Score

3-4 2

5+ 3

**Type of Study**

This question refers to the type of study the trial is. For example, IMPs being used within their licensed indication will be a lower risk than an IMP which is licensed but being applied in a novel way. If the IMP is not licensed at all, it will entail an even greater risk than both previous categories. Gene Therapy and Advanced Therapy Medicinal Products (ATMPs) will entail the highest risk category based on their novelty and level of unknown adverse events.

If multiple IMPs are used, then the IMP that has the highest risk should be used to score this question:

CTIMP licensed for use 1

Score

CTIMP licensed, new use 2

CTIMP not licensed 3

Gene Therapy or ATMPs 4

**Vulnerable Groups**

This question relates to whether the research will involve any vulnerable groups. If there are multiple vulnerable groups in the study, then the most vulnerable group should be used to score this question:

None involved 0

Score

Children 1

Children under 5 2

Mental Capacity 1

Prisoners 1

Young Offenders 1

**No of organisations/departments involved**

This question relates to the number of different departments or organisations that will be involved. Imaging, Pharmacy and Pathology should each be considered an individual department:

0-1 1

Score

2-3 2

3- 5 3

5+ 4

**Design**

This question relates to the design of the study. **If more than one is applicable** to the study, then the RGIT monitor should add up the scores to give a total figure:

RCT 1

Score

Open label 1

Single Blinded 1

Double Blinded 1

**Study Team and their experience**

A more experienced and qualified research team is less likely to make errors than a team conducting their first research project. Qualifications and experience of the main members of the team should be considered when answering this question:

Low 3

Score

Moderate 2

High 1

**Number of sites**

The more sites that a study is conducted in, the higher the chance of errors occurring. If there are international sites, these should be included in the scoring of this question:

0-1 1

Score

2-5 2

6- 10 3

10+ 4

**Length of study**

If a study is conducted for a longer period of time, there may be more changes to the study (e.g., staff changes) and therefore a greater risk of errors occurring. This question should be scored as follows:

< 1 year 1

Score

1-3 years 2

4+years 3

**Complexity**

The more complicated or complex the study, the greater the risk. This question should be scored as:

Simple 1

Score

Moderate 2

Complex 3

**Scoring Explained:**

A score of **11 - 15** is considered a low-risk study.

A score of **16 - 20** is considered a study similar to usual care.

A score of **21 - 26** is considered a study with substantial risk.

A score of **27 - 37** or a **first in mankind** study is considered a study with high risk.