EORTC
European Organisation for Research and Treatment of Cancer
AISBL International Non-Profit Association under Belgian law IVZW

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Risk-based assessment in cancer trials conducted by the EORTC

It is of critical importance for European clinical research that cancer patients of member states benefit from any new treatment that could potentially increase their life expectancy or improve quality of life.

However, it is essential to quantify the potential risks associated with patient participation into a clinical trial as compared to their risks when treated with the standard of care in the same indication, in terms of safety, rights, and privacy.

The EORTC is currently developing a risk based scoring system in order to evaluate and quantify the risk level of the patient's involvement into a new clinical trial coordinated by the EORTC. This will involve developing optimal strategies for quality management, including extent of on-site monitoring, accelerated data tracking and processing, and central data monitoring.

The EORTC initial results derived from the scoring sheet attached suggest the identification of three levels of risks (high, moderate, and low).

Based on nearly 50 years of experience in Cancer clinical trials, the EORTC has an extensive clinical trials database that will serve for additional testing and validation of the scoring sheet.

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EORTC Study Risk Assessment
Scoring Sheet under evaluation at EORTC

The global risk score evaluated for a given study will be the sum of all individual scores associated to the following criteria.

item	Risk categories / risk score	4	3	2	1	0
A	**Study characteristics**					
1	Phase	Phase I	phase II	Randomized phase II	Phase III	Survey
2	Blind type	Double-blind	Single blind		Open label	
3	Patient's characteristics	Children	Elderly		18-70	
B	**Treatment**					
4	Surgery (x2)*	Investigational		standard		No surgery
5	Radiotherapy (x2)*	Investigational		standard		No radiotherapy
6	Drug administration	IV	IM / SC	Oral		No drug
7	Combination of drugs	≥ 3	2	1		0
8	IMP licensing status (x2)*	Not licensed		Licensed in other tumor type	Licensed in study tumor type at other dose/route	NA
9	IMP safety data	No clinical data available	Phase 1 data only	Phase 2 data	Phase 3 data	NA
10	Pharmacological class agent (x2)*	Unknown (new class of agent)		Known (similar agents under investigation)	Well known (similar agents licensed)	NA
C	**Safety**					
11	Expected related SAEs cases (x2)*	> 20 % of pats	> 10 % of pats	> 5% of pats	> 2% of pats	≤ 2% of pats
12	Statistical analysis (for phase 2)	Final analysis only			Interim analysis: 2-step design	NA
13	Statistical analysis (for phase 3)	Final analysis only		Interim analysis	IDMC	NA

(x2): the risk score associated to these criteria is doubled*