Welcome to a pocket guide to interpreting clinical data.

This guide gives simple definitions of clinical terms and is designed to help you get to the facts more quickly. It is written with cancer in mind – but can be applied to any trial, regardless of therapeutic area.
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Over the past 20 years, we’ve witnessed groundbreaking advances in the treatment of cancer, thanks to our growing understanding of the disease. As a result, we’re seeing changes in the measures of efficacy (endpoints) used in clinical trials.
There are an ever-expanding variety of endpoints used in clinical trials. Like people, they each have a different job to do. Below are some of the classic endpoints used in trials of cancer medicines, as well as some modern endpoints.

### Classic endpoints

#### The Heavyweight
**Overall Survival (OS)**

OS is the historical ‘gold standard.’ It is a measure of how long people with cancer live. As there are increasing treatment options and people with certain tumours live longer, it is more difficult to measure OS.

#### The Scout
**Progression-Free Survival (PFS)**

PFS measures the time until disease worsening or death.

#### The Sleuth
**Response Rate (RR)**

One of the classic endpoints, defined as the percentage of people whose cancer has decreased by a defined amount. This is commonly based on a level of tumour shrinkage viewed on medical scans, like a sleuth examining evidence through a magnifying glass.
Modern endpoints

The Investigator
Minimal Residual Disease (MRD)

A high tech spin on traditional detective work. MRD is an endpoint that uses newer, highly sensitive technologies to search for traces of certain blood cancers where traditional tests may have come up clean.

The Surgeon
Pathological Complete Response (pCR)

An assessment of the efficacy of a medicine given prior to surgery, defined as no cancer detectable at the time of surgery.

The Enthusiast
Quality of Life (QoL)

QoL is a complex concept involving many aspects of a person’s satisfaction with life; ranging from the ability to work to the experience of certain side effects. Unlike other endpoints, it is based on what patients report.

The Disruptor
Immune Related Response Criteria (irRC)

Like a disruptive innovator in the tech world, irRC is shaking things up in the world of endpoints. It is a fundamentally different way of assessing anti-tumour efficacy that accounts for the unique response patterns seen with immunotherapies.
What is a Kaplan-Meier (KM) graph?

Improvements in measures are often assessed by the median and are plotted on Kaplan-Meier (KM) curves. This is the most commonly used method for representing life table data. It ranks patient survival according to how long they have been in the study, rather than when they entered the study. It recalculates the survival rate whenever an end event (e.g. death) occurs in the data set, i.e. when a change occurs rather than at fixed intervals.

Kaplan-Meier (KM) survival estimates are often used to compare survival between groups, producing a hazard ratio (HR).
A hazard ratio (HR) is a calculation of the ratio of the chance of something harmful happening (such as death or cancer recurrence) in one entire treatment group, divided by the risk of the event in the comparison treatment group. In other words, it looks at the difference at all points along the Kaplan-Meier curve, not just at the midway point.

A HR of 1 means there is no difference between the groups, a HR of 2 is double the risk and a HR of 0.5 is half the risk.
A confidence interval (CI) indicates the value if the trial assessed every patient with that disease rather than just the number of people in the trial. In other words, CI suggests how sure (or confident) we are of the range that encompasses the true population value.
For further information about interpreting clinical data, we would encourage you to review the following resources:


This guide deliberately simplifies some concepts to make them clearer and easier for journalists to use.