

## Progress on Prostate Cancer Research

February 2020

Advancements in prostate cancer research provide hope for finding a cure and lead to the discovery of new treatments to minimize the impact of a man's prostate cancer and maximize his quality of life. This regular *Hot SHEET* supplement includes some of the latest research from the Prostate Cancer Foundation ([www.pcf.org](http://www.pcf.org)).

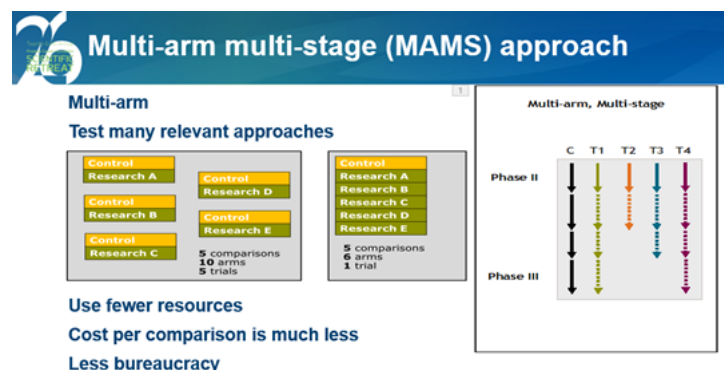
The PCF is the world's leading philanthropic organization funding and accelerating prostate cancer research. Founded in 1993, the PCF has raised more than \$745 million and provided funding to more than 2,000 research programs at nearly 200 cancer centers and universities.

### Focus on STAMPEDE: A Uniquely Designed Clinical Trial is Delivering Practice-Changing Findings to Patients (Part 1)

Clinical trials are necessary to determine whether a new treatment is superior to the current standard of care for improving the length and/or quality of patients' lives. To receive FDA approval, a new treatment must typically proceed through three phases of clinical trials. The final phase (phase 3) trials can be complex, time consuming, and very costly, but are typically required for regulatory approval of a new treatment.

In an effort to streamline and reduce the cost and number of patients needed to test multiple treatments in phase 3 trials, investigators in the UK and Switzerland devised the STAMPEDE trial. **Regular readers of the Hot Sheet have doubtless seen reports of previous results coming out of STAMPEDE - but it's worthwhile to take a minute to appreciate the design of this key trial.** It's a multi-arm, multi-stage randomized phase 3 clinical trial that is comparing several different treatment regimens in prostate cancer patients who are starting long-term ADT. These are men with node-positive or metastatic disease, who are newly diagnosed or relapsing after previous primary treatment with surgery or radiation.

The unique design of the STAMPEDE trial allows for many test arms to be added over time and compared to men treated with a contemporary standard-of-care from a single ongoing control arm. **Because of the trial design, only a single "control" arm is needed for many comparison arms, significantly reducing the number of patients that would have been needed if each treatment had been tested in an independent trial requiring its own control arm (see graphic).** The primary outcome measure is overall survival.



STAMPEDE is headed by Professor Nicholas James, Prostate and Bladder Cancer Research Team Leader at the Institute of Cancer Research, London, and Consultant Clinical Oncologist at the Royal Marsden Hospital. **Since 2005, the trial has enrolled over 11,000 men into the equivalent of 11 randomized control trials and made several practice-changing findings.** Importantly, the trial demonstrated that adding new arms to the trial is fast and feasible. When the trial initiated in 2005, there was one control arm and five comparator arms. Between 2011 and 2019, five additional comparator arms have been added. While the control arm is ongoing, the first seven comparator arms have been completed.

Activating new clinical trials can be time consuming, as much paperwork and institutional and governmental reviews and approvals are needed, which must be performed for all clinical sites involved. **However, the design of STAMPEDE significantly reduced the time to open new treatment arms at all of the centers involved (currently over 120).** Thus far, over 3,000 investigators in the UK and Switzerland have contributed to this trial. New trial designs and data evaluation methods are being employed to efficiently add new trial arms in new international centers, including the U.S., Germany, Australia and New Zealand.

Next month, we will present an overview of some of STAMPEDE's results to date.

For more information visit [www.pcf.org](http://www.pcf.org), email [info@pcf.org](mailto:info@pcf.org), or call 1-800-757-2873.