

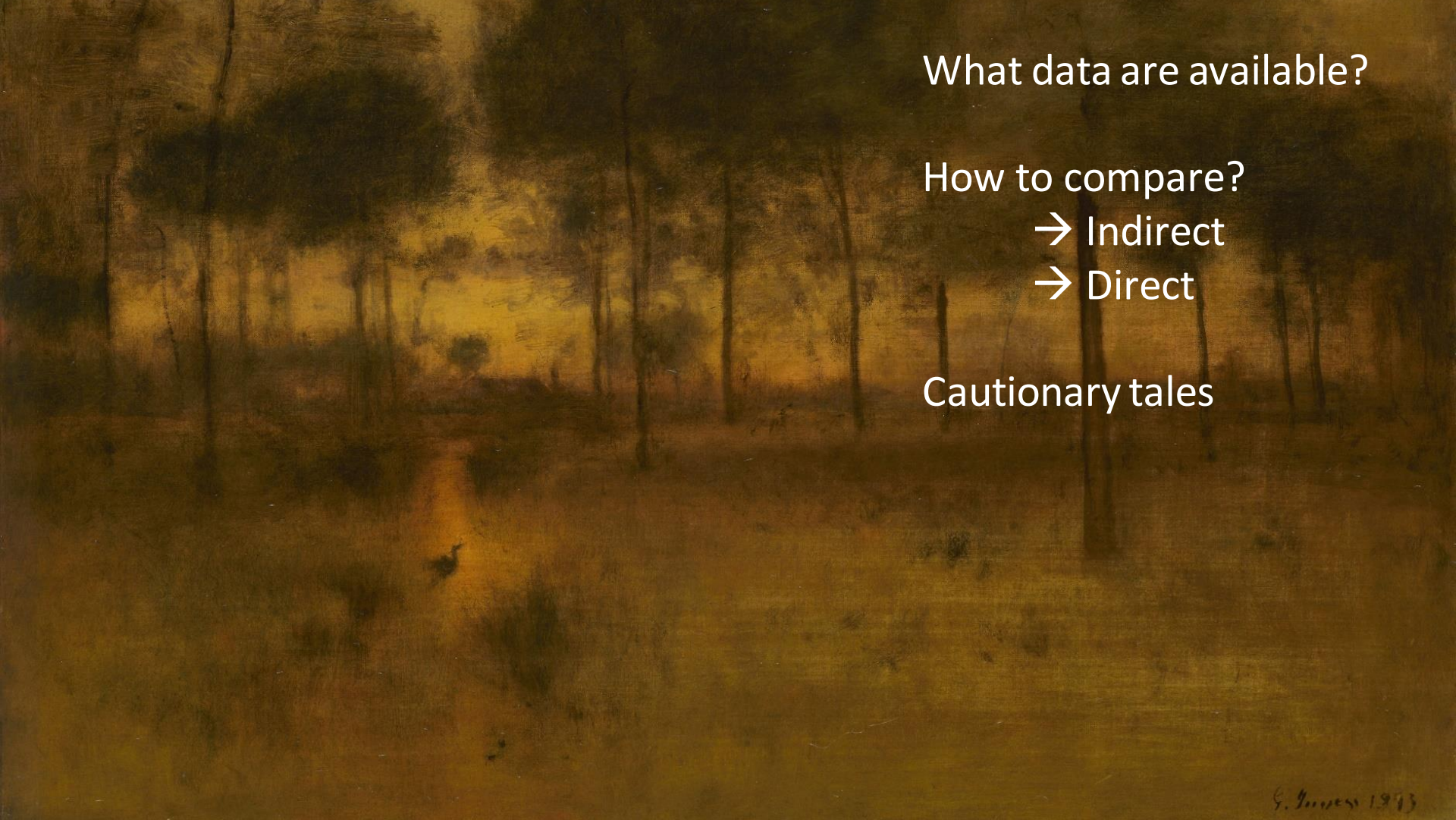
Addition of AR pathway inhibitors vs. docetaxel: Statisticians' perspective

Matthew Sydes

MRC Clinical Trials Unit at UCL

London

30-Aug-2019



What data are available?

How to compare?

→ Indirect

→ Direct

Cautionary tales

Disclosures

Relevant research funding to institute:

- Astellas
- Clovis Oncology
- Janssen
- Novartis
- Pfizer
- Sanofi-Genzyme

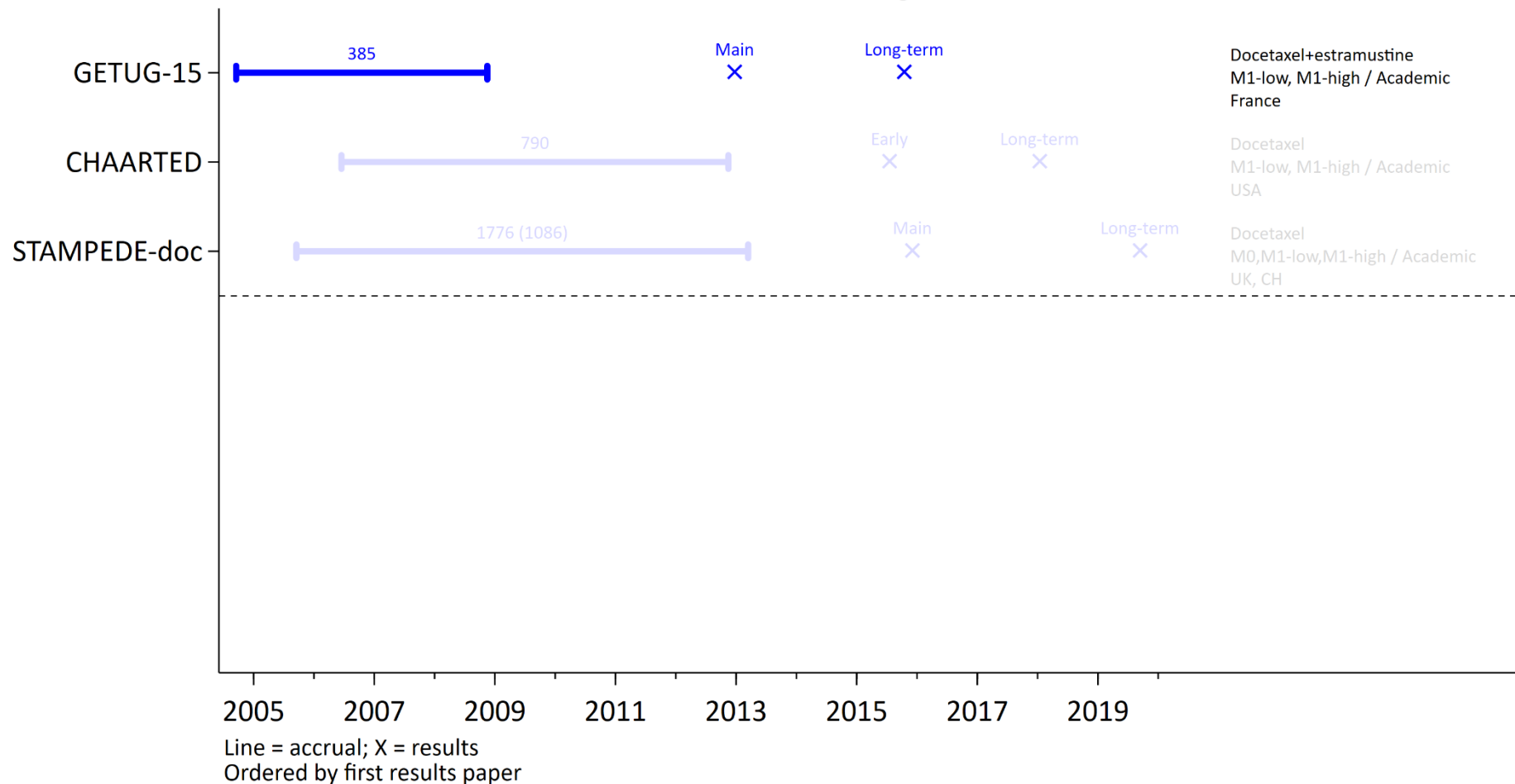
Honoraria and travel:

- Eli Lilly
- Janssen

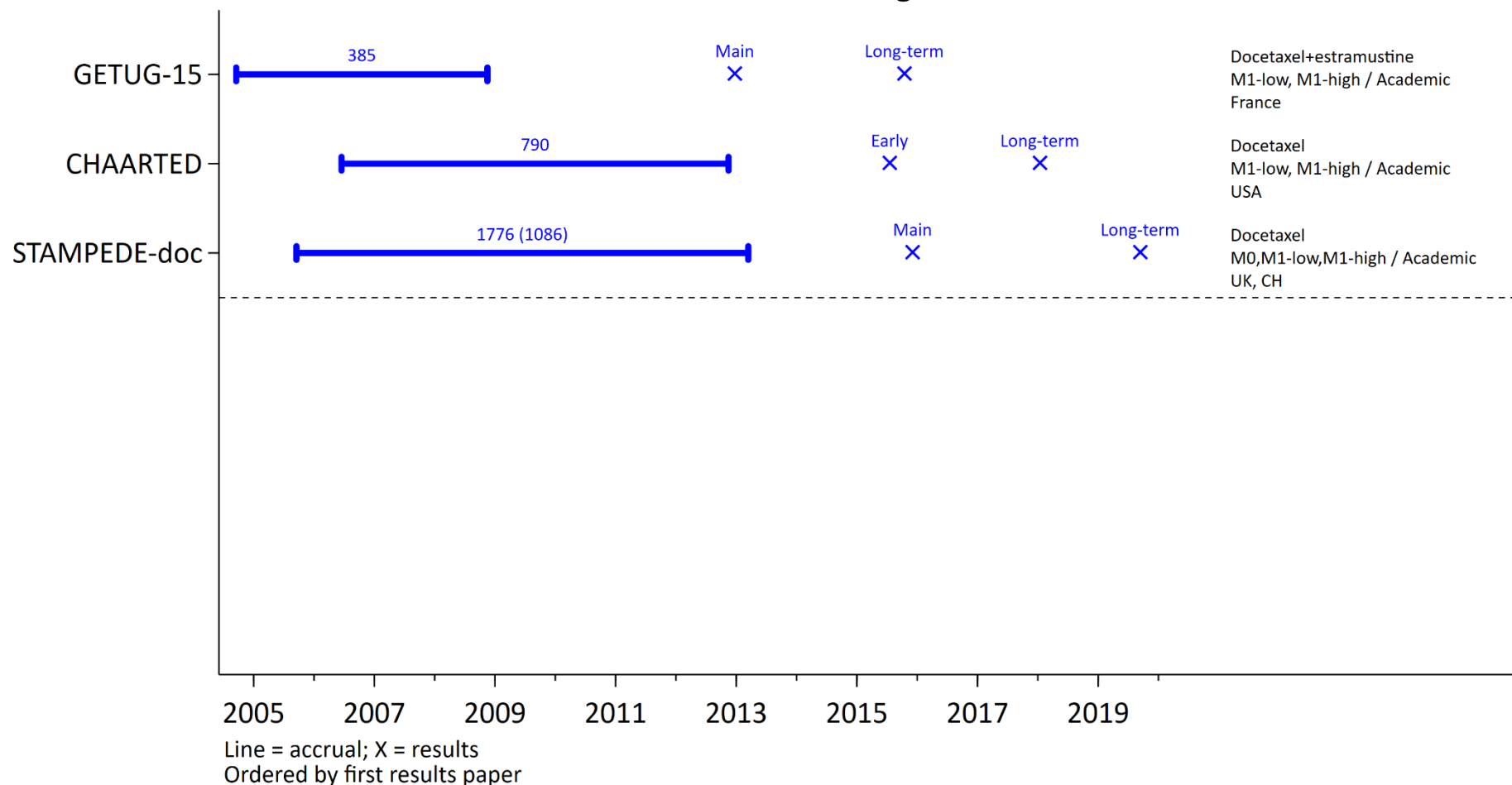
Statistician on:

- PR04
- PR05
- PR07
- RADICALS-RT
- RADICALS-HT
- RT01
- STAMPEDE:doc
- STAMPEDE:doc+ZA
- STAMPEDE:ZA
- STAMPEDE:cel
- STAMPEDE:cel+ZA
- STAMPEDE:abi
- STAMPEDE:M1-RT

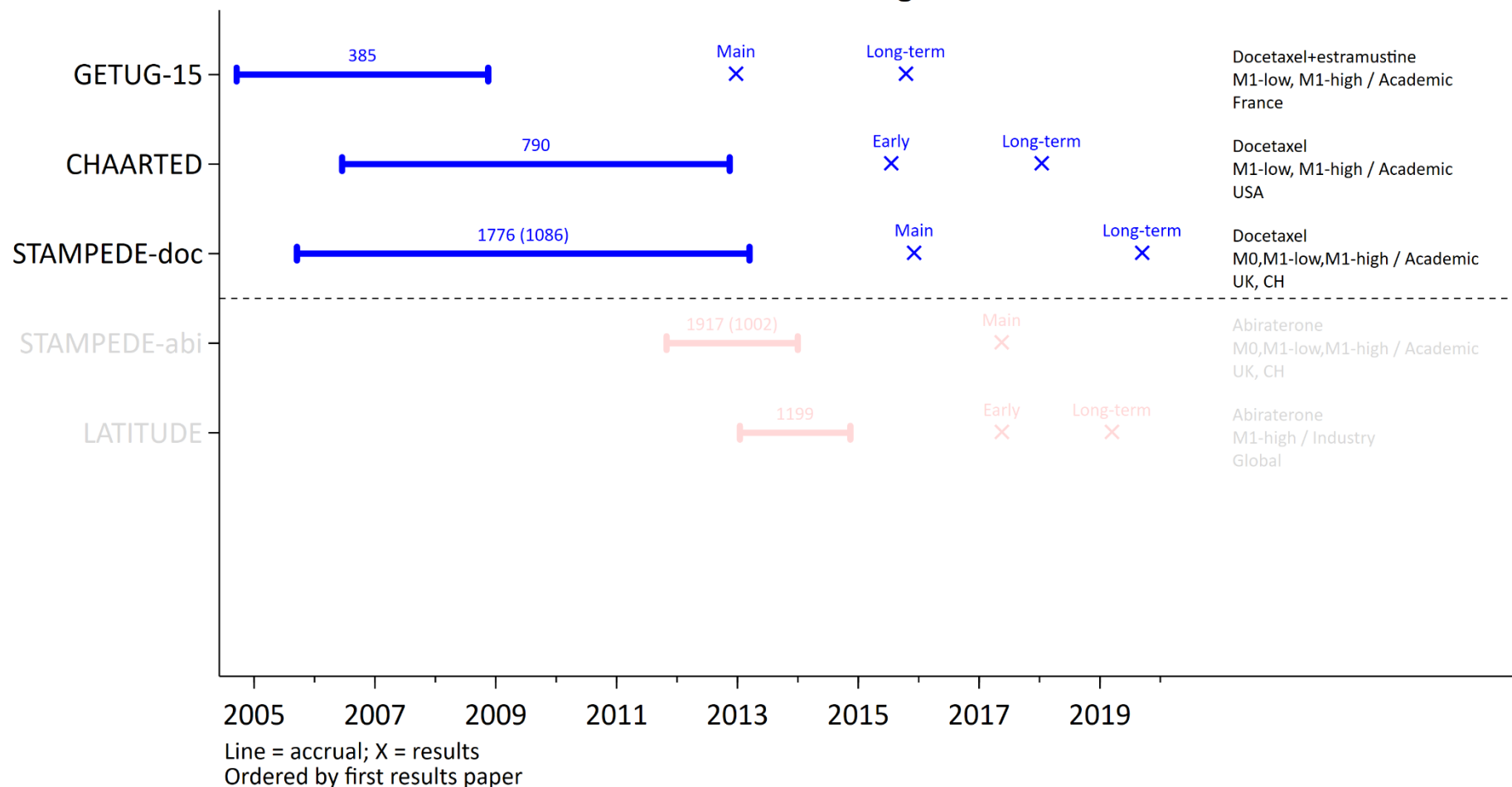
mHSPC trials: docetaxel and AR RCTs -- Timing of accrual and results



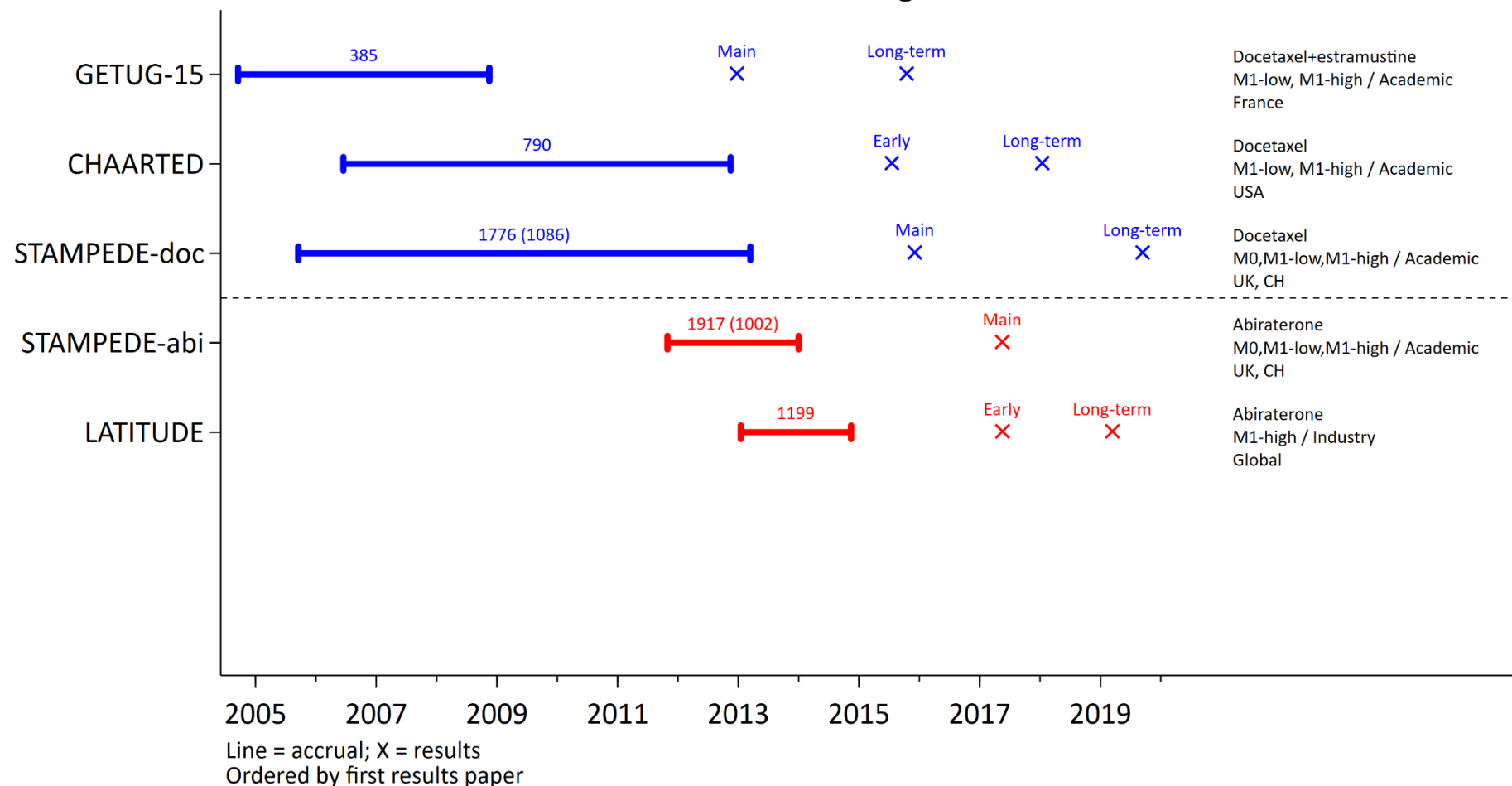
mHSPC trials: docetaxel and AR RCTs -- Timing of accrual and results



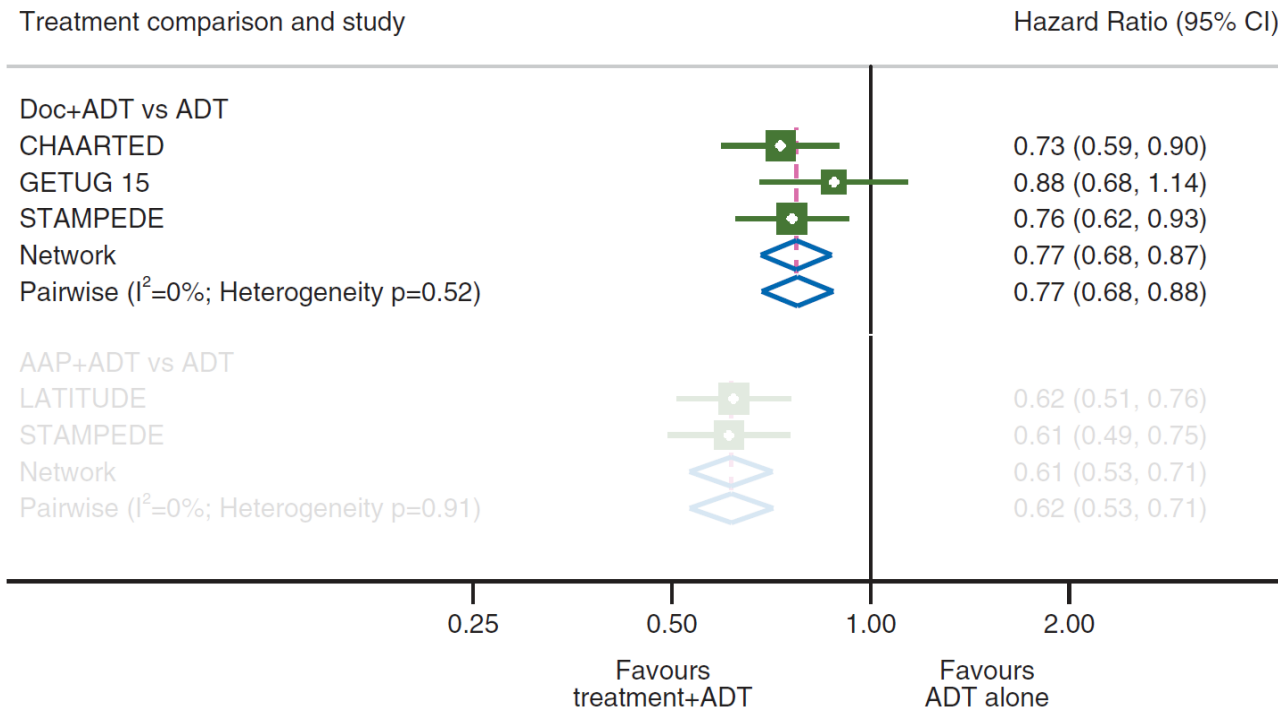
mHSPC trials: docetaxel and AR RCTs -- Timing of accrual and results



mHSPC trials: docetaxel and AR RCTs -- Timing of accrual and results



STOPCAP network meta-analysis (2018) – indirect comparison

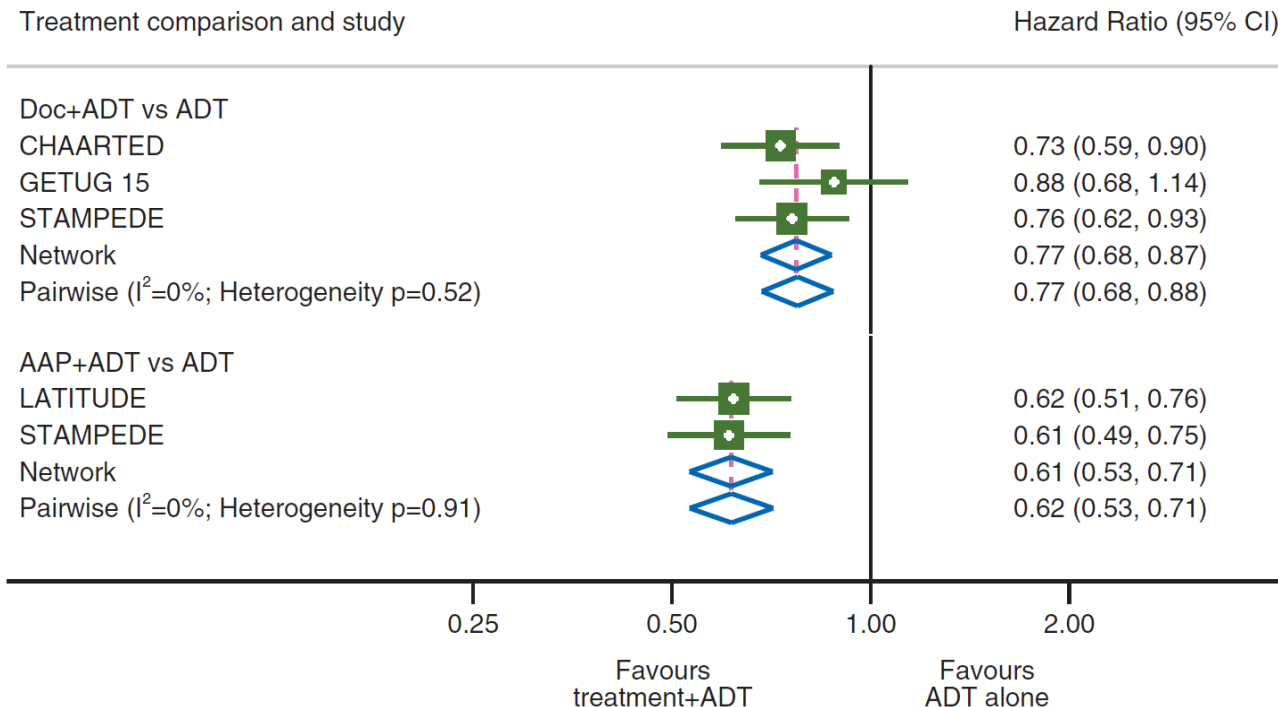


Overall survival

Published data network meta-analysis



STOPCAP network meta-analysis (2018) – indirect comparison

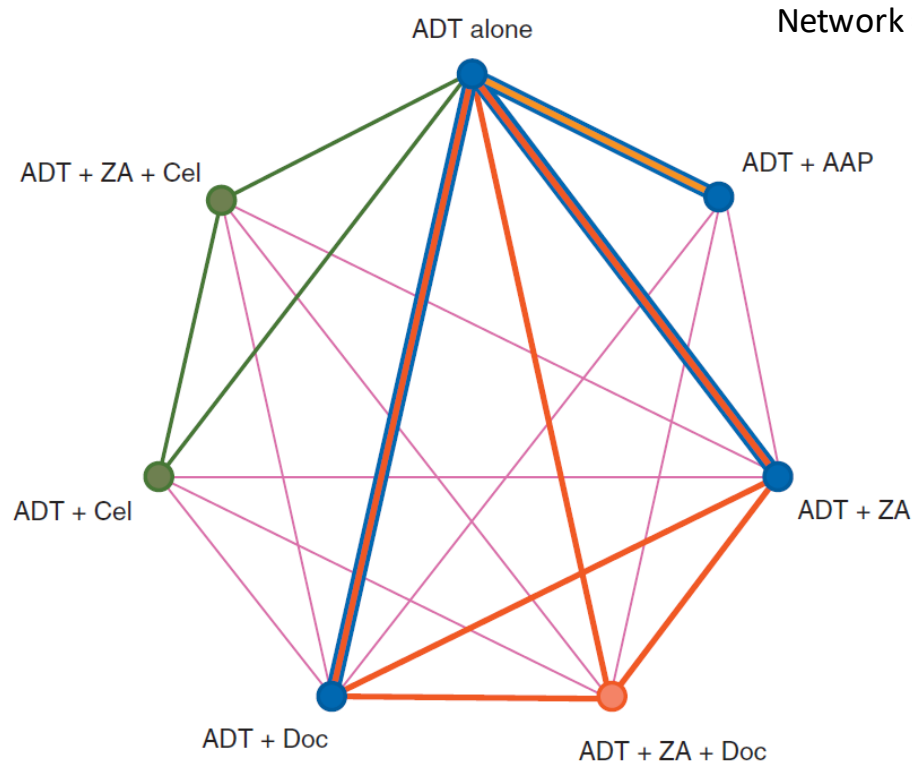


Overall survival

Published data network meta-analysis



STOPCAP network meta-analysis (2018) – indirect comparison

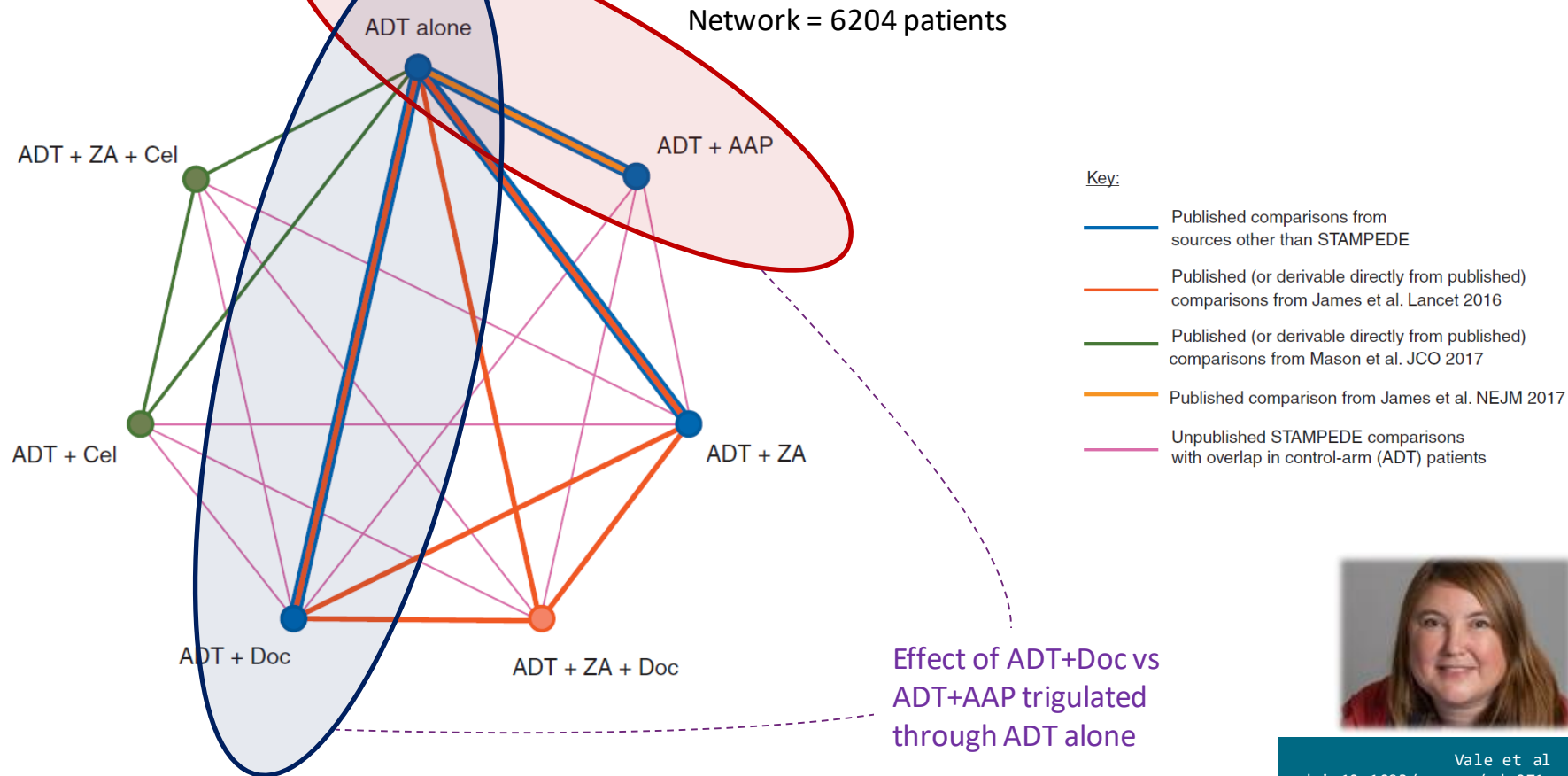


Key:

- Published comparisons from sources other than STAMPEDE
- Published (or derivable directly from published) comparisons from James et al. Lancet 2016
- Published (or derivable directly from published) comparisons from Mason et al. JCO 2017
- Published comparison from James et al. NEJM 2017
- Unpublished STAMPEDE comparisons with overlap in control-arm (ADT) patients



STOPCAP network meta-analysis (2018) – indirect comparison



STOPCAP network meta-analysis (2018) – indirect comparison

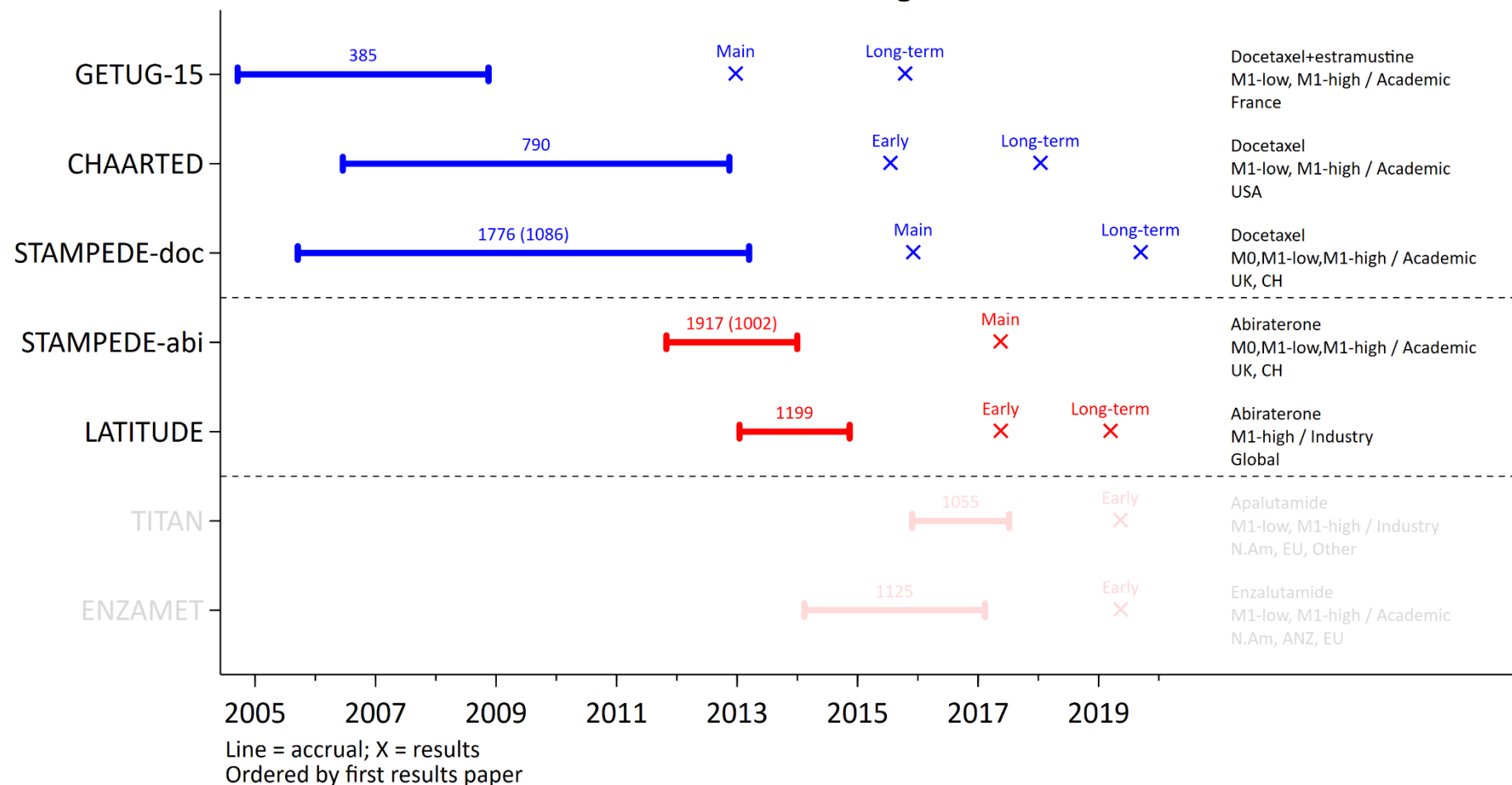
Table 3. Treatment ranking (% probability) and SUCRA values based on overall survival results

	AAP	Doc	ZA + Doc	ZA + Cel	ZA	Cel	ADT alone
Best	94.2	0.7	1.3	3.8	0.0	0.0	0.0
Second best	5.3	34.9	25.5	33.0	0.3	1.0	0.0
Third best	0.4	36.8	30.3	27.0	2.4	3.1	0.0
Fourth best	0.1	23.6	30.8	23.9	12.2	9.3	0.1
Fifth best	0.0	3.8	9.3	9.3	48.7	26.0	2.9
Sixth best	0.0	0.2	2.6	2.5	31.3	33.6	29.8
Worst	0.0	0.0	0.2	0.5	5.1	27.0	67.2
SUCRA	1.0	0.7	0.6	0.6	0.3	0.2	0.1

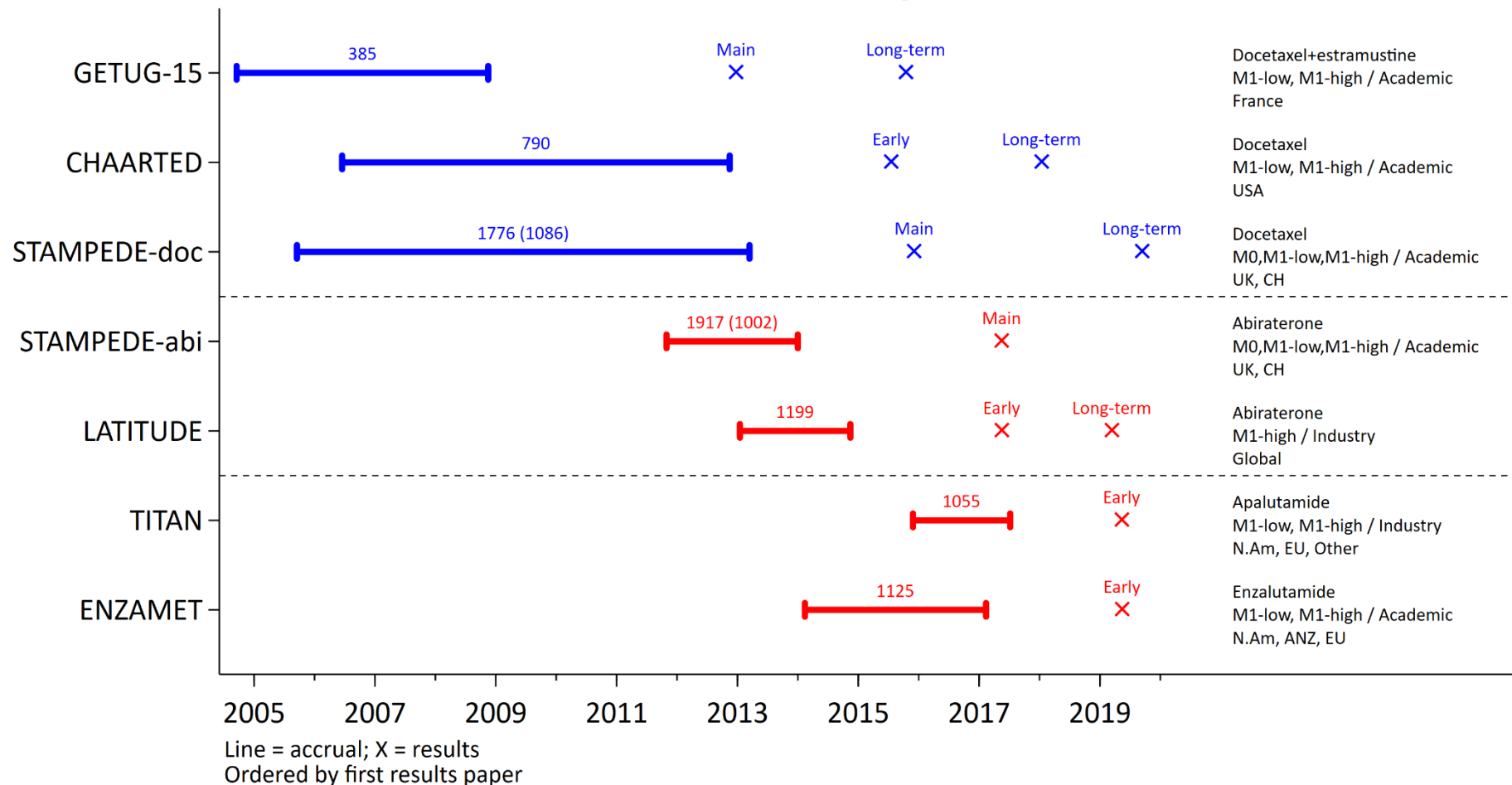
AAP, abiraterone acetate plus prednisolone/prednisone; ADT, androgen-deprivation therapy; Cel, celecoxib; Doc, docetaxel; SUCRA, surface under the cumulative rank; ZA, zoledronic acid.

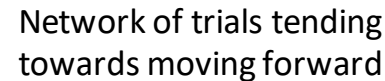


mHSPC trials: docetaxel and AR RCTs -- Timing of accrual and results



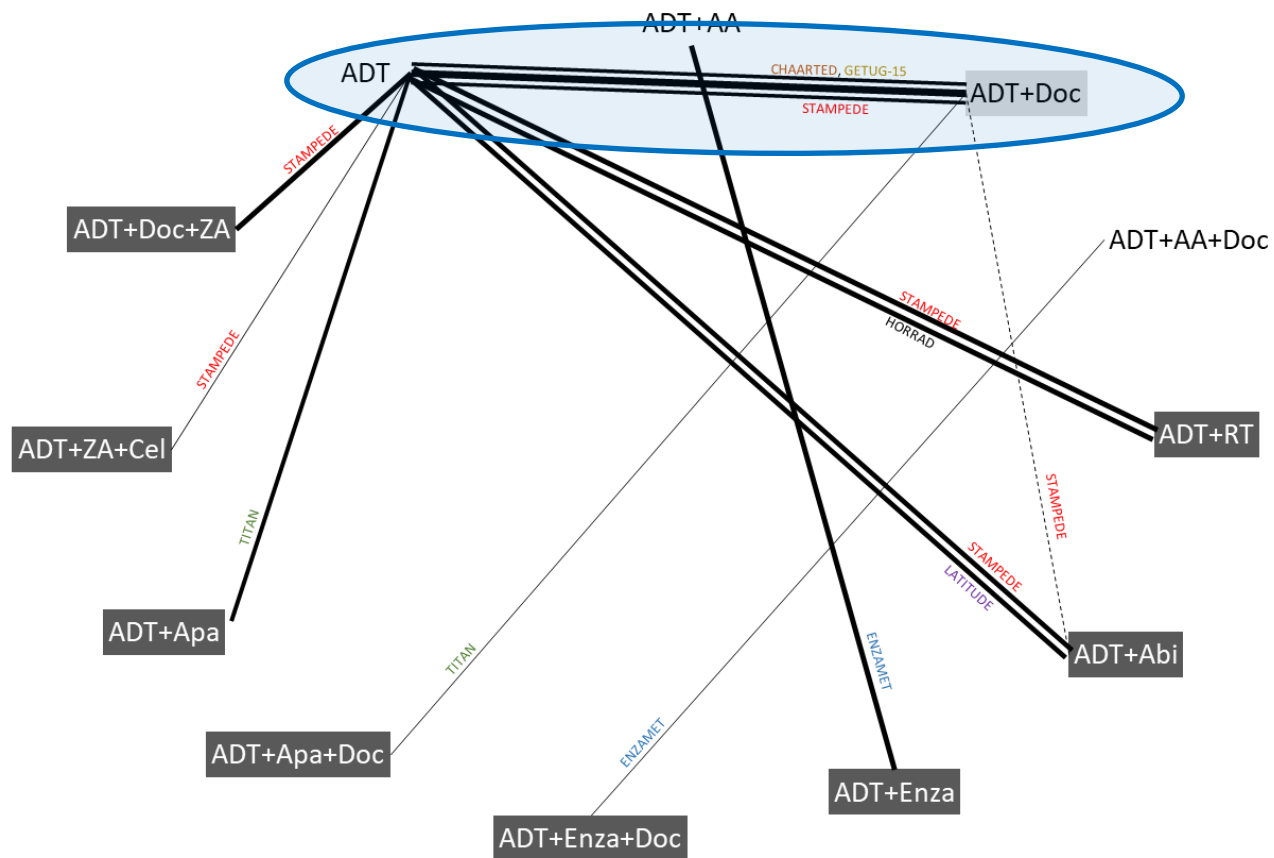
mHSPC trials: docetaxel and AR RCTs -- Timing of accrual and results





Network of trials tending
towards moving forward

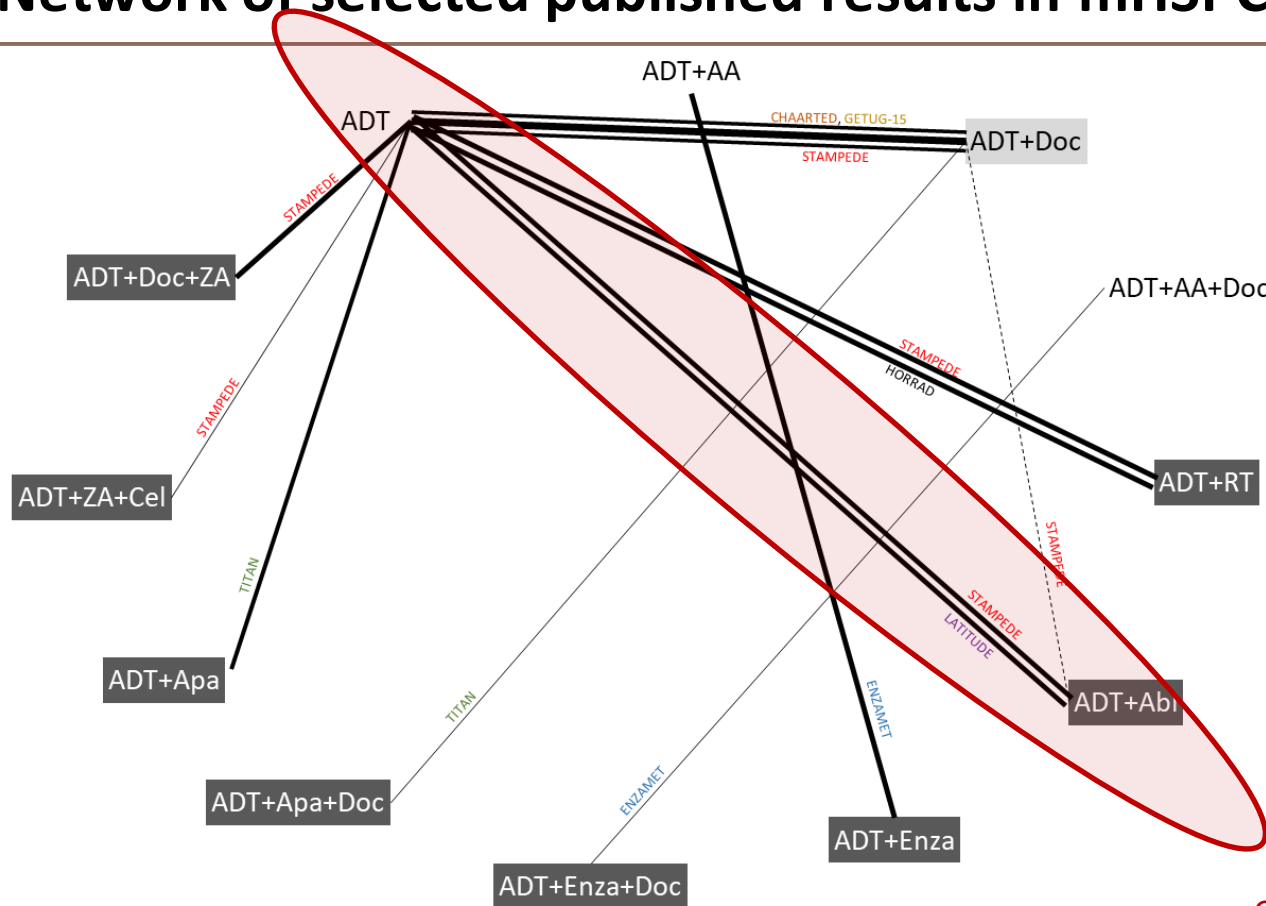
Network of selected published results in mHSPC



Network of trials tending towards moving forward

Comparison of “Adding Docetaxel”

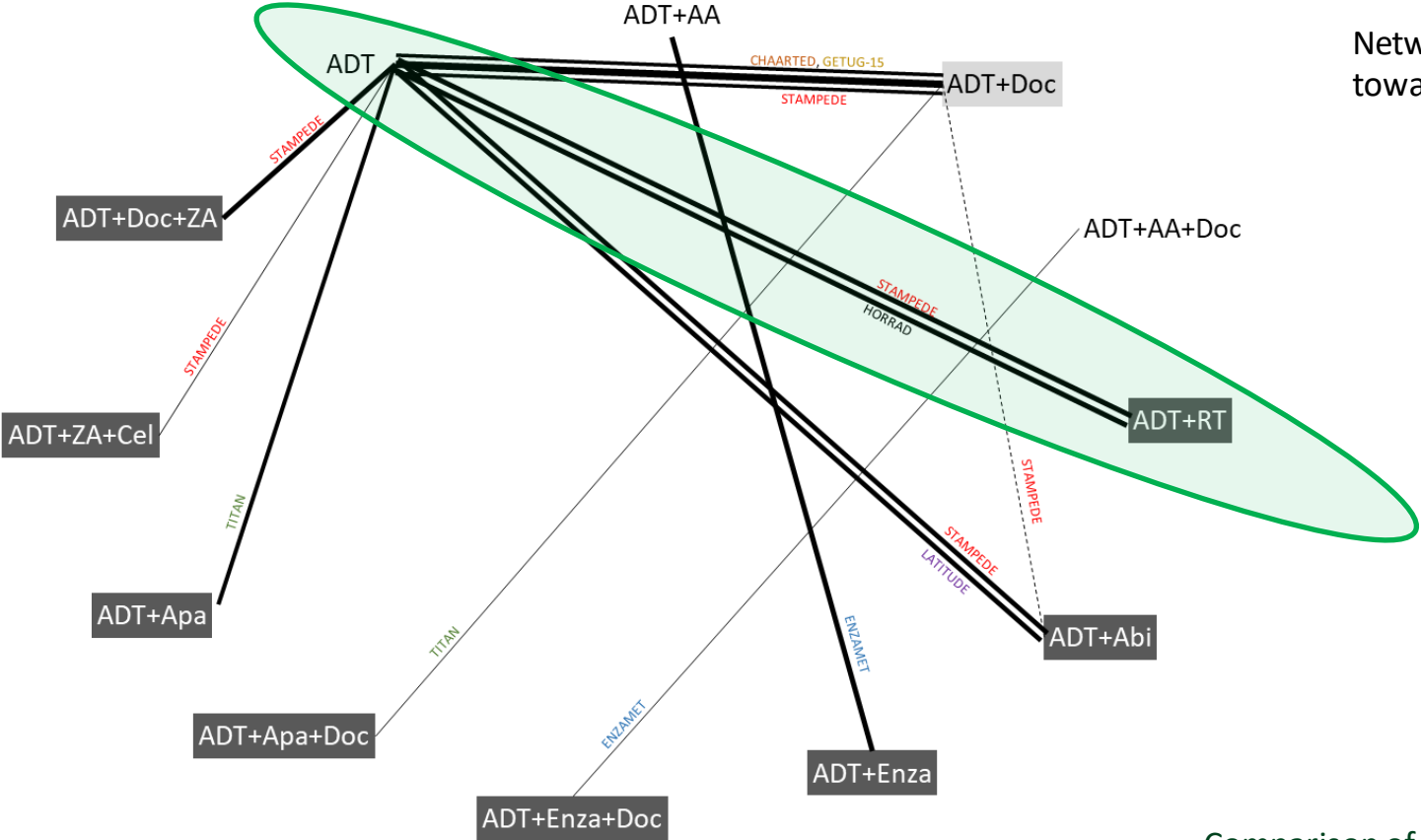
Network of selected published results in mHSPC



Network of trials tending towards moving forward

Comparison of “Adding Abiraterone”

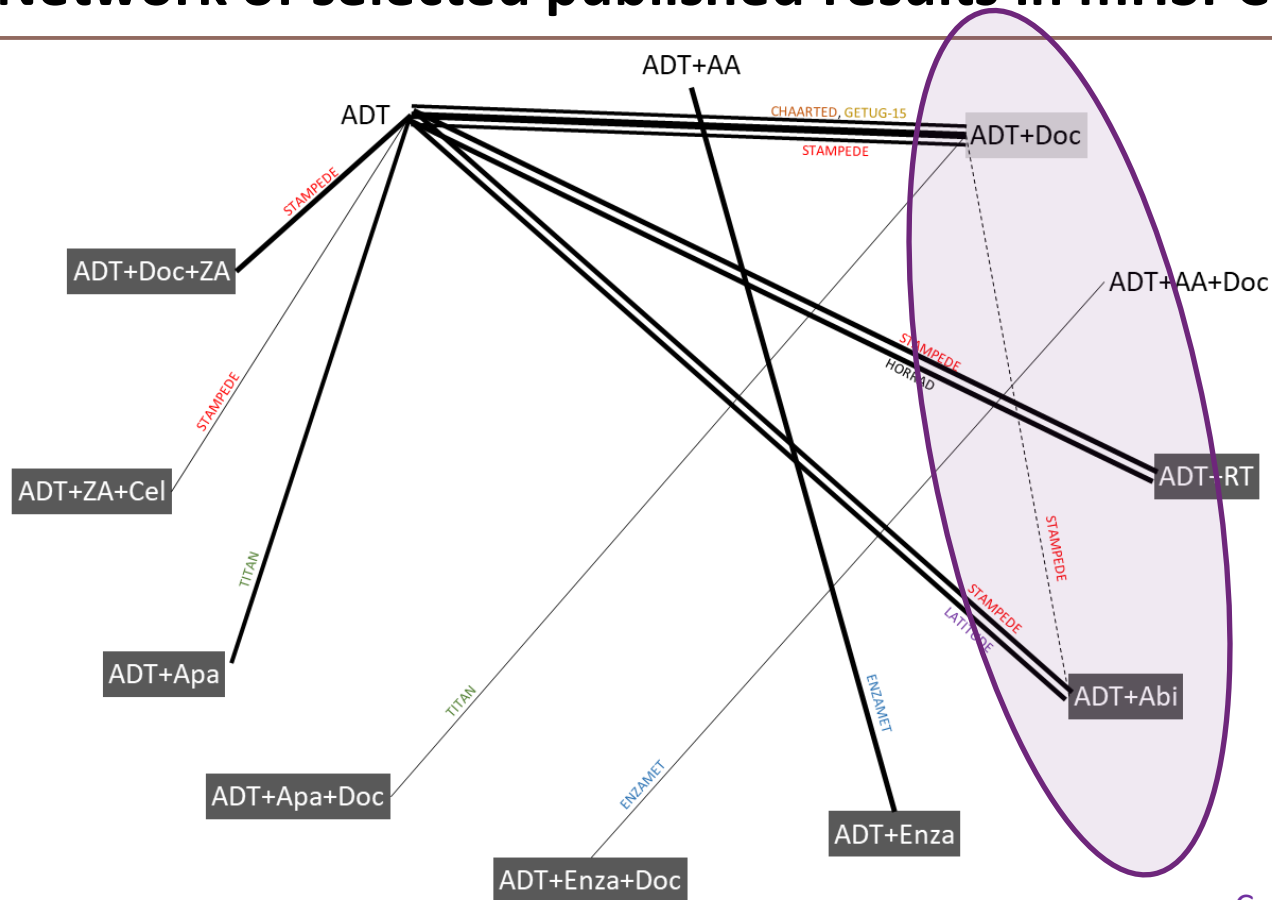
Network of selected published results in mHSPC



Network of trials tending towards moving forward

Comparison of “Adding Radiotherapy”

Network of selected published results in mHSPC

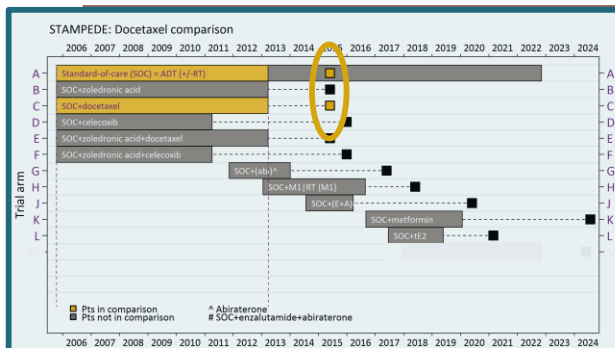


Network of trials tending towards moving forward

Only **directly comparative** data of adding docetaxel or AR pathway inhibitor

Comparison of “Adding Docetaxel” OR “Adding abiraterone”

Data from STAMPEDE leading to **direct** comparison



SOC+DocP vs **SOC** (n=1776) [2:1]

M1 61%

Age 65 yr median

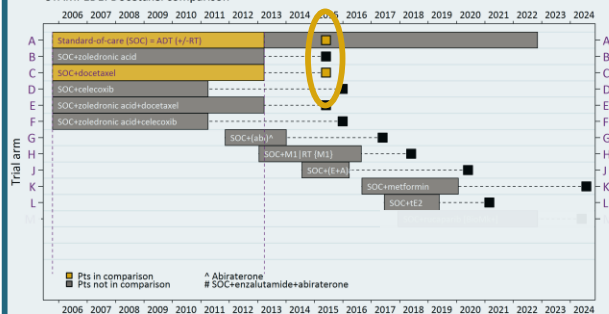
PSA 68 ng/ml median

Accrue Oct-2005 to Mar-2013

Freeze May-2015

Data from STAMPEDE leading to **direct** comparison

STAMPEDE: Docetaxel comparison



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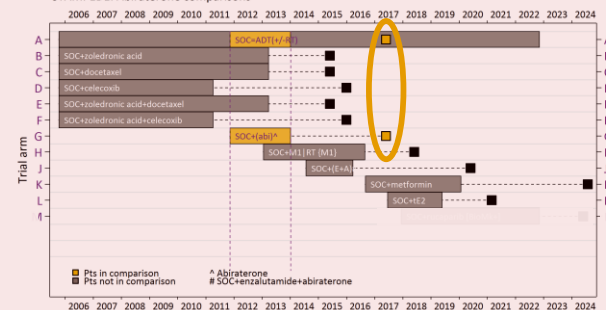
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STAMPEDE: Abiraterone comparisons



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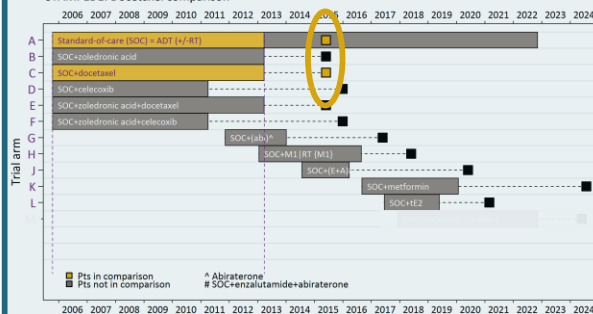
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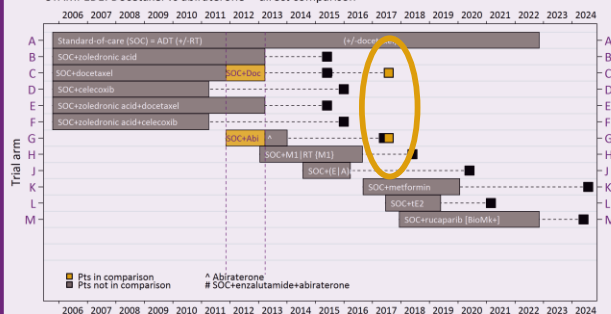
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STAMPEDE: Docetaxel vs abiraterone -- direct comparison



SOC+DocP vs **SOC+AAP** (n=566) [1:2]

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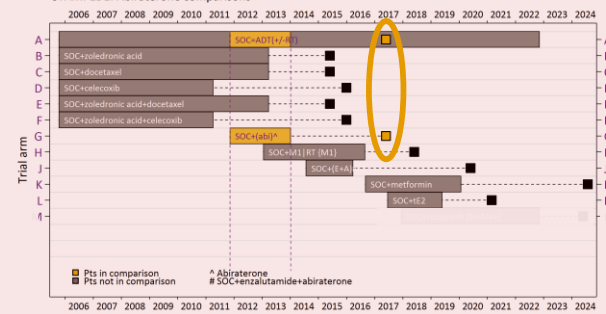
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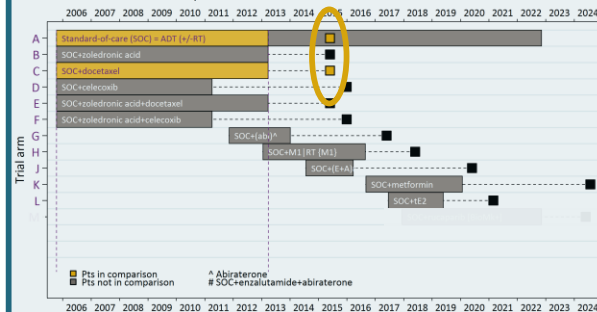
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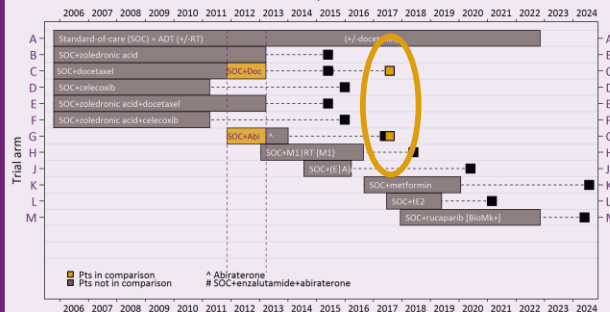
Accrue Oct-2005 to Mar-2013

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HR (95%CI) 0.78 (0.66, 0.93)

P-value 0.006

STAMPEDE: Docetaxel vs abiraterone -- direct comparison



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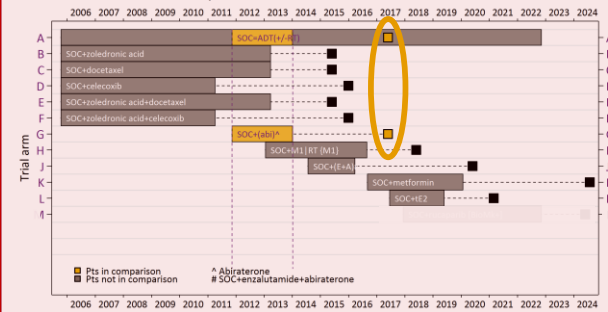
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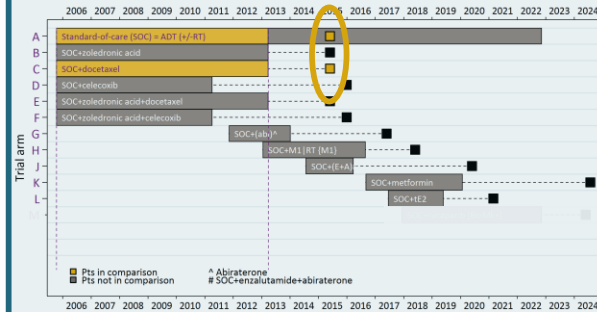
doi: 10.1016/S0140-6736(15)01037-5

Articles

Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE): survival results from an adaptive, multiarm, multistage.

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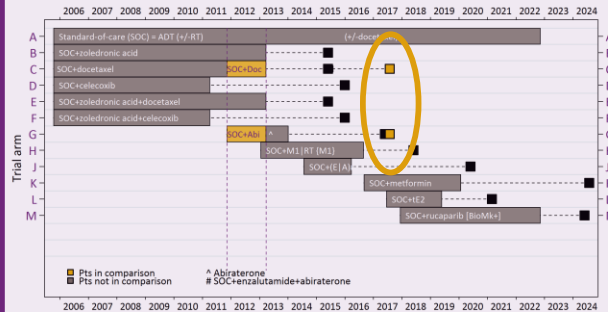
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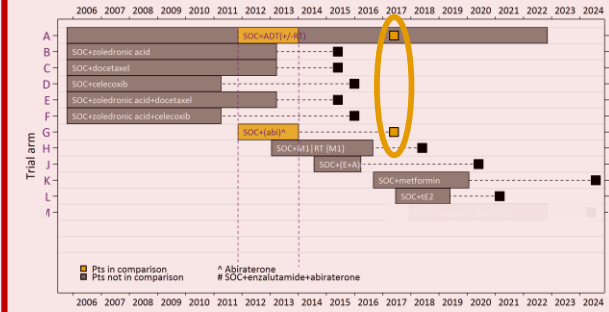
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doi: 10.1016/S0140-6736(15)01037-5

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Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE): survival results from an adaptive, multiarm, multistage.



doi: 10.1056/NEJMoa1702900

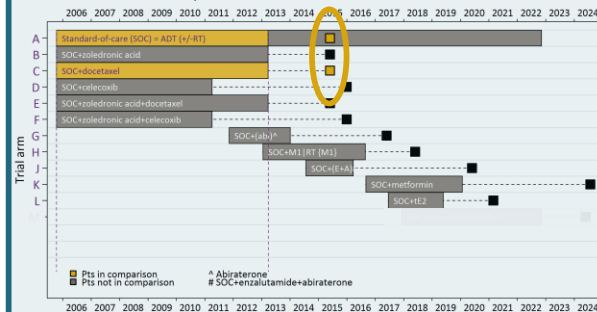
NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

Abiraterone for Prostate Cancer Not Previously Treated with Hormone Therapy

Data from STAMPEDE leading to **direct** comparison

STAMPEDE: Docetaxel comparison



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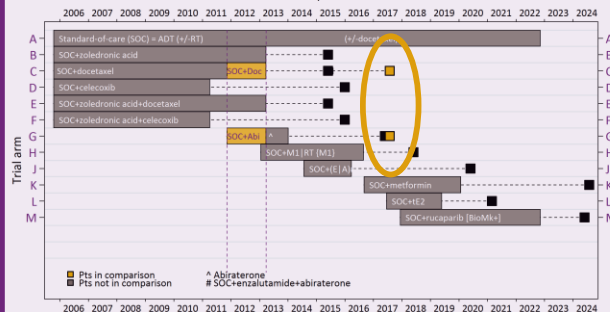
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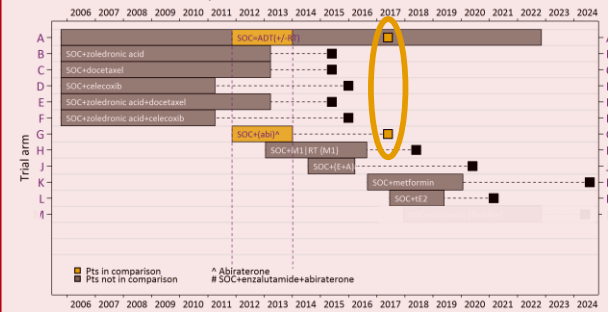
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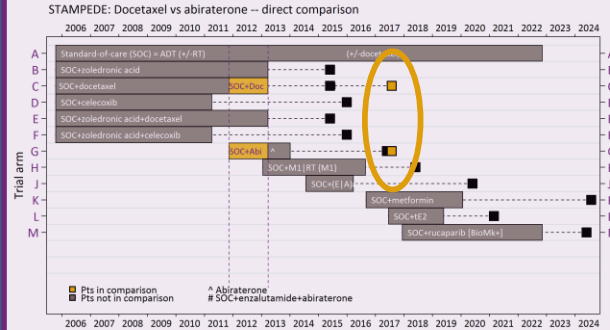
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Abiraterone or docetaxel to long-term hormone therapy for prostate cancer: directly randomised data from the STAMPEDE multi-arm, multi-stage platform protocol

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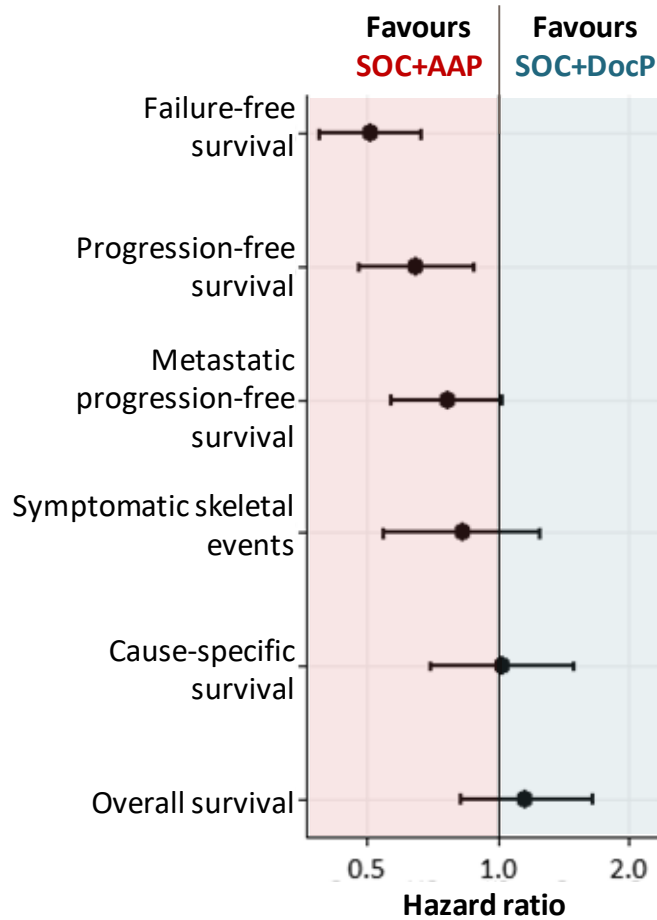
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ESMO

ARTICLE

Abiraterone or docetaxel to long-term hormone therapy for prostate cancer: directly randomised data from the STAMPEDE multi-arm, multi-stage platform protocol

Summary



Head-to-head data in 566 M0 and M1 pts
(Recruited Nov-2011 to Mar-2013)

Strong evidence favouring AAP

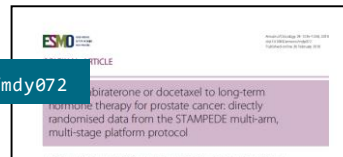
Weak evidence favouring AAP

→ Proportionately different time spent in each disease state

No good evidence of a difference

Toxicity profiles quite different and well known

doi: 10.1093/annonc/mdy072



HR<1 favours adding a bicalutamide
HR>1 favours adding docetaxel

A note of caution

- ‡ Key eligibility criteria in STAMPEDE unchanged in 15 years
- ‡ Subtle shifts over time in patients joining any trial
- ‡ Some shifts in standard practice and management, especially relating to second-line care

Newly-diagnosed

Any of:

- Metastatic
- Node-Positive
- ≥ 2 of: Stage T3 or T4
PSA $\geq 40\text{ng/ml}$
Gleason 8, 9 or 10

Relapsing after previous RP or RT

Any of:

- Metastatic
- Node-positive
- PSA $\geq 4\text{ng/ml}$, rising & doubling time $< 6\text{m}$
- PSA $\geq 20\text{ng/ml}$

All patients

Written informed consent
Fit for all protocol treatment
Fit for follow-up

Full criteria

www.stampedetrial.org

A note of caution

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• Metastatic
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Relapsing after previous RP or RT

Any of:
• Metastatic
• Node-positive
• PSA ≥4ng/ml, rising & doubling time <6m
• PSA ≥20ng/ml

All patients

Written informed consent
Fit for all protocol treatment
Fit for follow-up

Full criteria

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KEY MESSAGE:

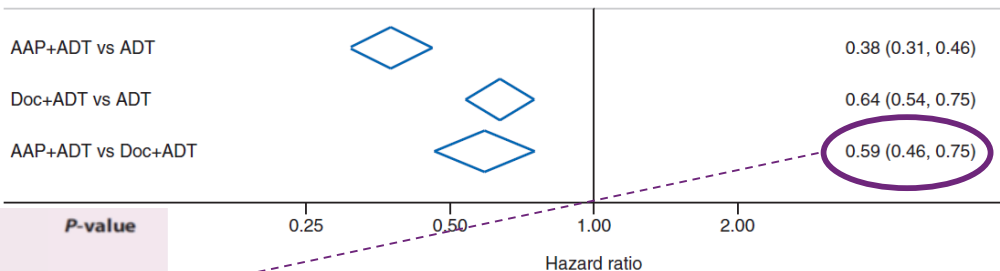
If must be careful within 1 consistent protocol,
must be really careful trying to understand differences across protocols!

STAMPEDE & STOPCAP

STAMPEDE: M1 – all outcome measures

Outcome measure	Patient group	Events/Pts SOC + DocP	Events/Pts SOC + AAP	Hazard ratio ^a (95% CI)	P-value
Failure-free survival ^b	M1	79/115	109/227	0.56 (0.42–0.75)	<0.001
Progression-free survival ^b	M1	62/115	94/227	0.69 (0.50–0.95)	0.023
Metastatic progression-free survival ^c	M1	61/115	100/227	0.76 (0.55–1.04)	0.085
Freedom from symptomatic skeletal events	M1	34/115	58/227	0.82 (0.53–1.25)	0.351
Overall survival	M1	38/115	89/227	1.13 (0.77–1.66)	0.528
Outcome measure	Patient group	Events/Pts SOC+Doc	Events/Pts SOC+AAP	Sub-hazard ratio ^d (95% CI)	P-value
Death from prostate cancer ^e	M1	36/115	80/227	1.05 (0.71–1.56)	0.807
Death from other causes ^f	M1	2/115	9/227	1.91 (0.43–8.41)	0.393

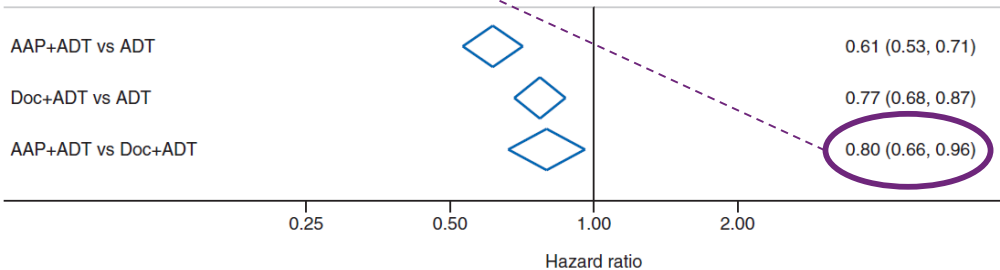
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STOPCAP: M1 – Failure-free survival

doi: 10.1093/annonc/mdy071

STOPCAP: M1 – Overall survival



All graphs:

HR<1 favours adding a biraterone

HR>1 favours adding docetaxel

STAMPEDE & STOPCAP: 2 ways to estimate same problem

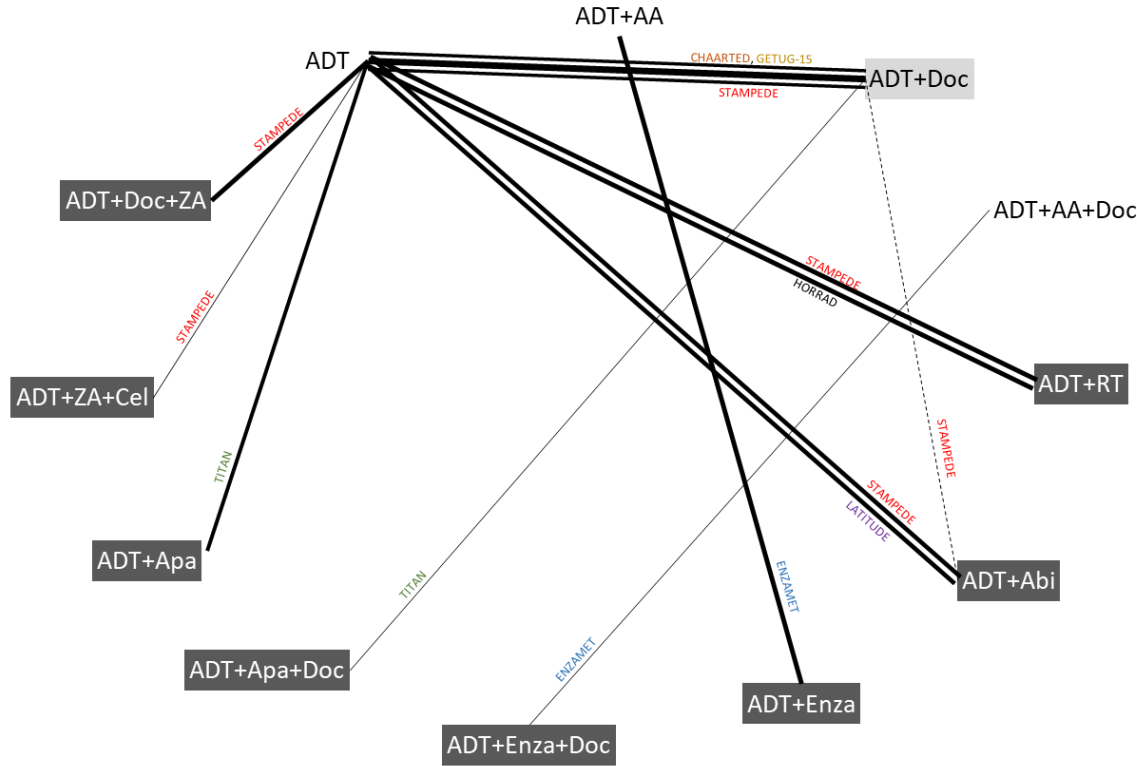
‡ STAMPEDE **direct** comparison:

- ‡ 566 patients
- ‡ Short time window: Nov-2011 to Mar-2013
- ‡ Consistent assessment methods

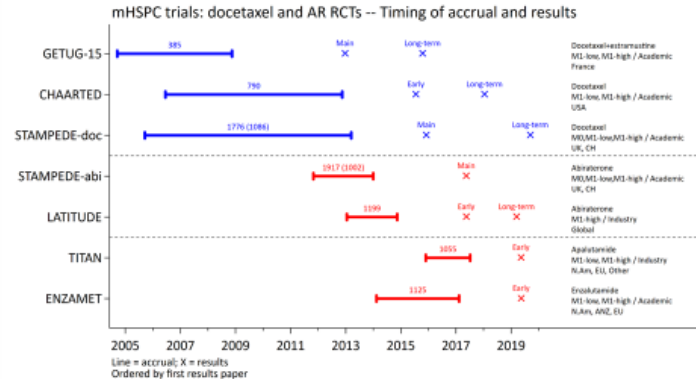
‡ STOPCAP **indirect** comparison:

- ‡ ~6000 patient network
- ‡ Long time window: Oct-2005 to Jan-2014
- ‡ Data from multiple trials

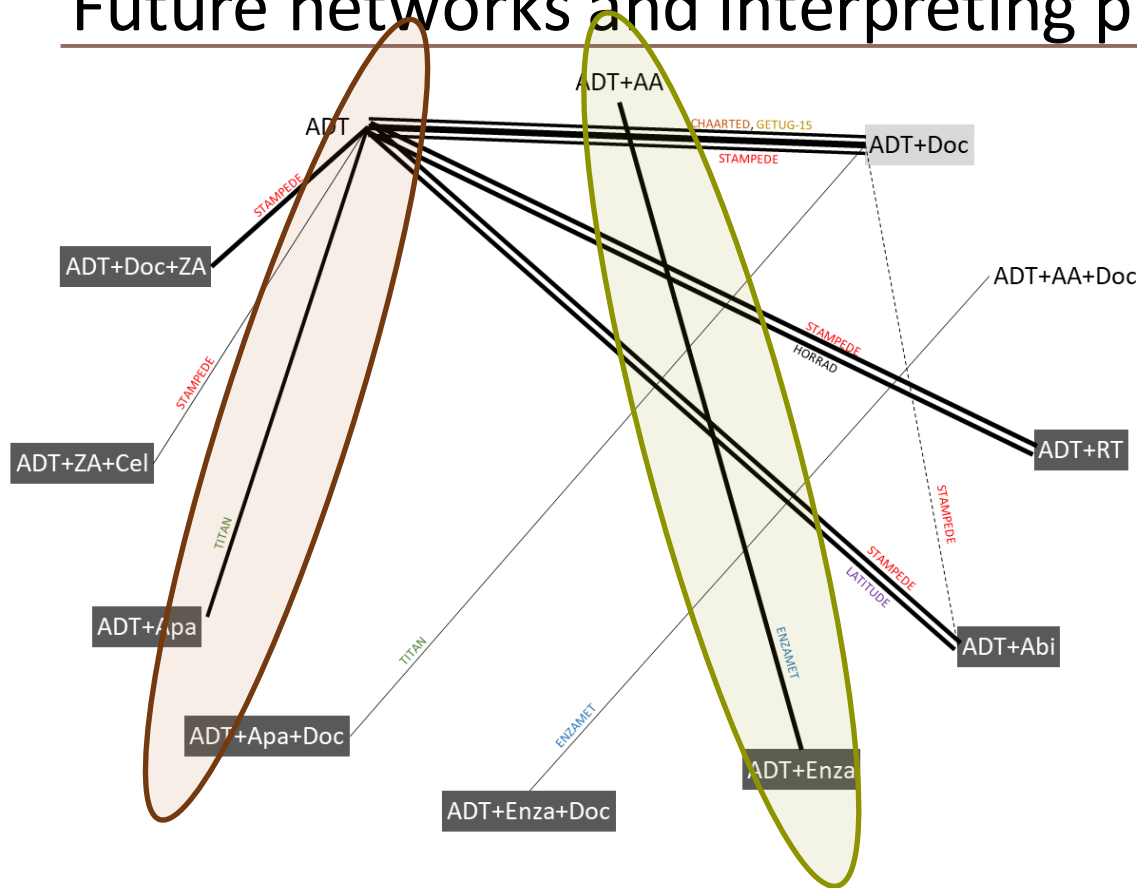
Future networks and interpreting published data



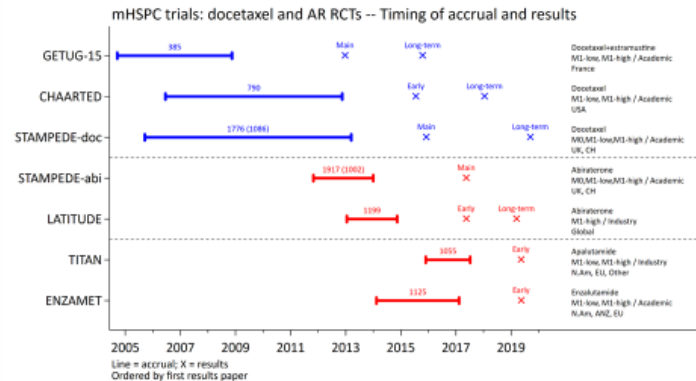
- ✚ Timing to recruitment
(proxy for many things including access to treatment at relapse)
- ✚ Geography of recruitment
- ✚ Use of docetaxel in standard-of-care



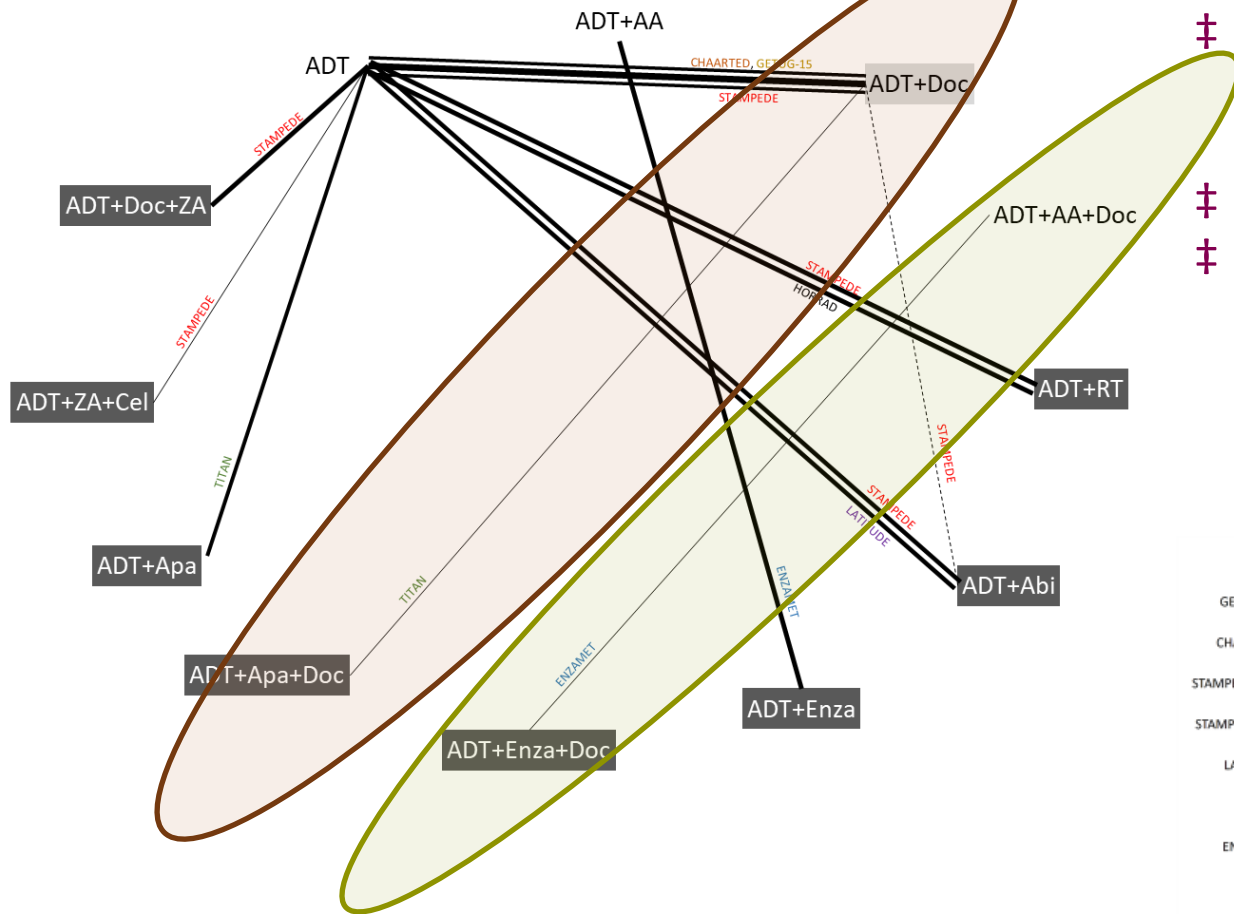
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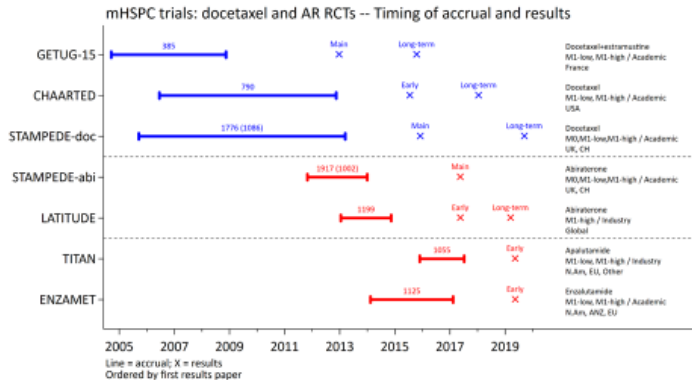
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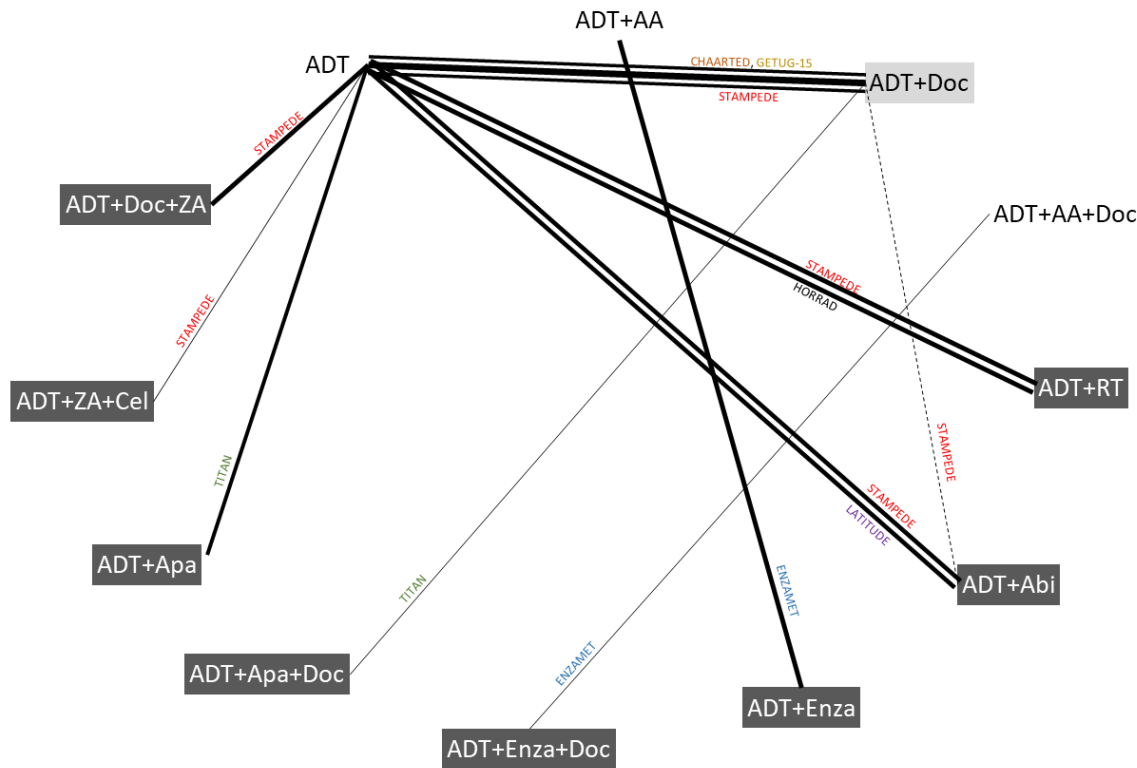
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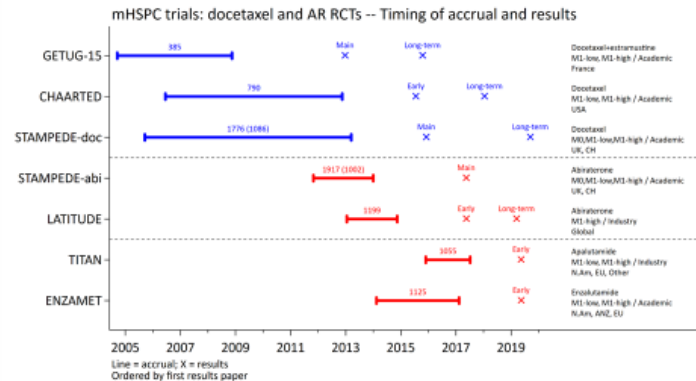
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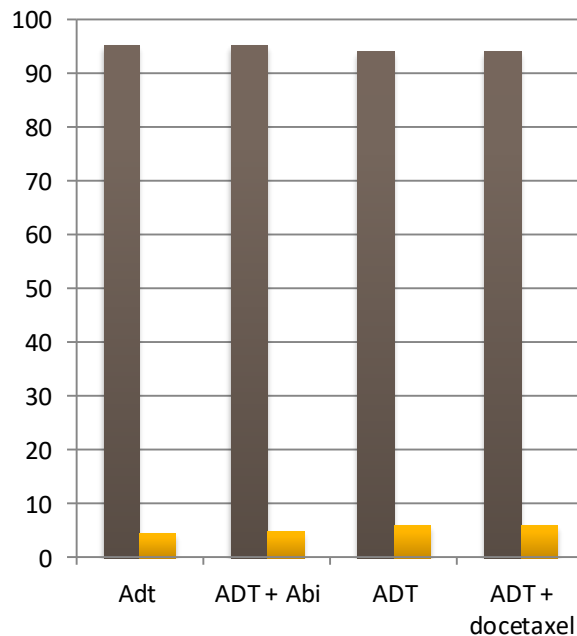
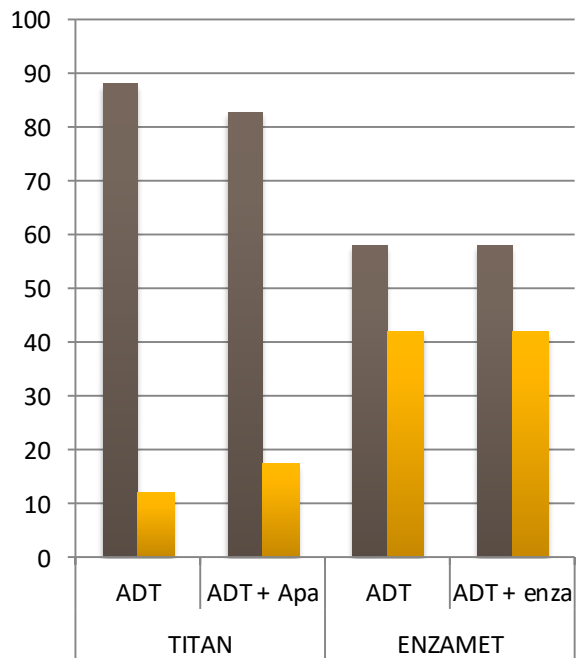


- ‡ Timing to recruitment
(proxy for many things including access to treatment at relapse)
- ‡ Geography of recruitment
- ‡ Use of docetaxel in standard-of-care
- ‡ Use of previous local therapy
- ‡ Use of metastatic volume or burden as stratifier (entry or analyses)



Future networks and interpreting published data

Reported prior therapy in TITAN, ENZAMET and STAMPEDE

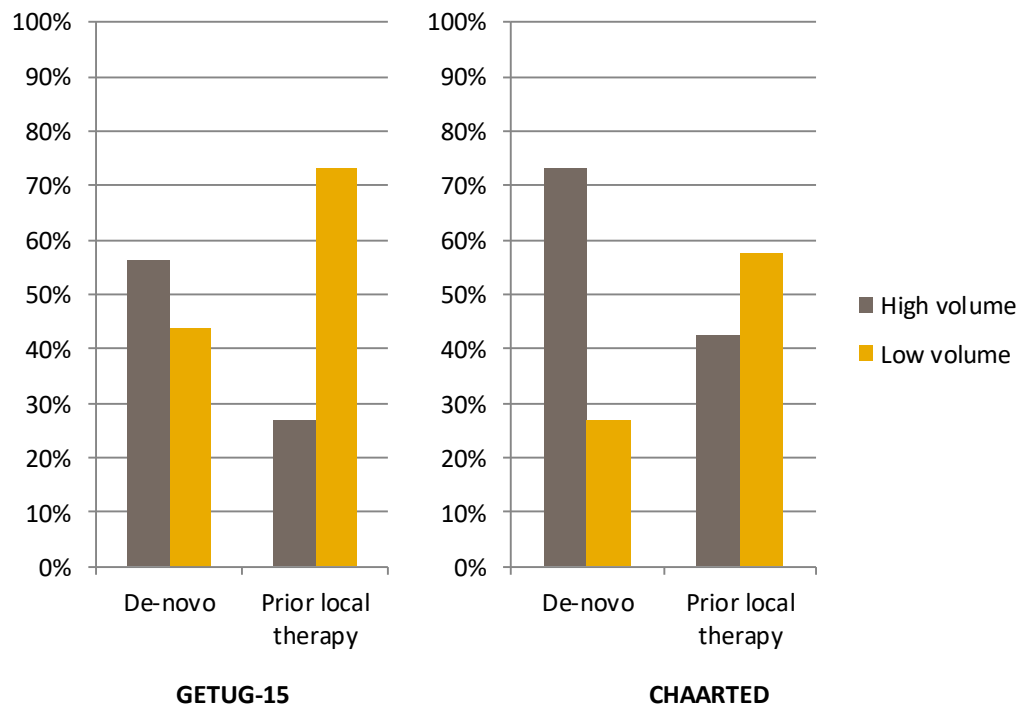


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- ‡ Use of docetaxel in standard-of-care
- ‡ Use of previous local therapy
- ‡ Use of metastatic volume or burden as stratifier (entry or analyses)

■ Primary
■ Previous Rx

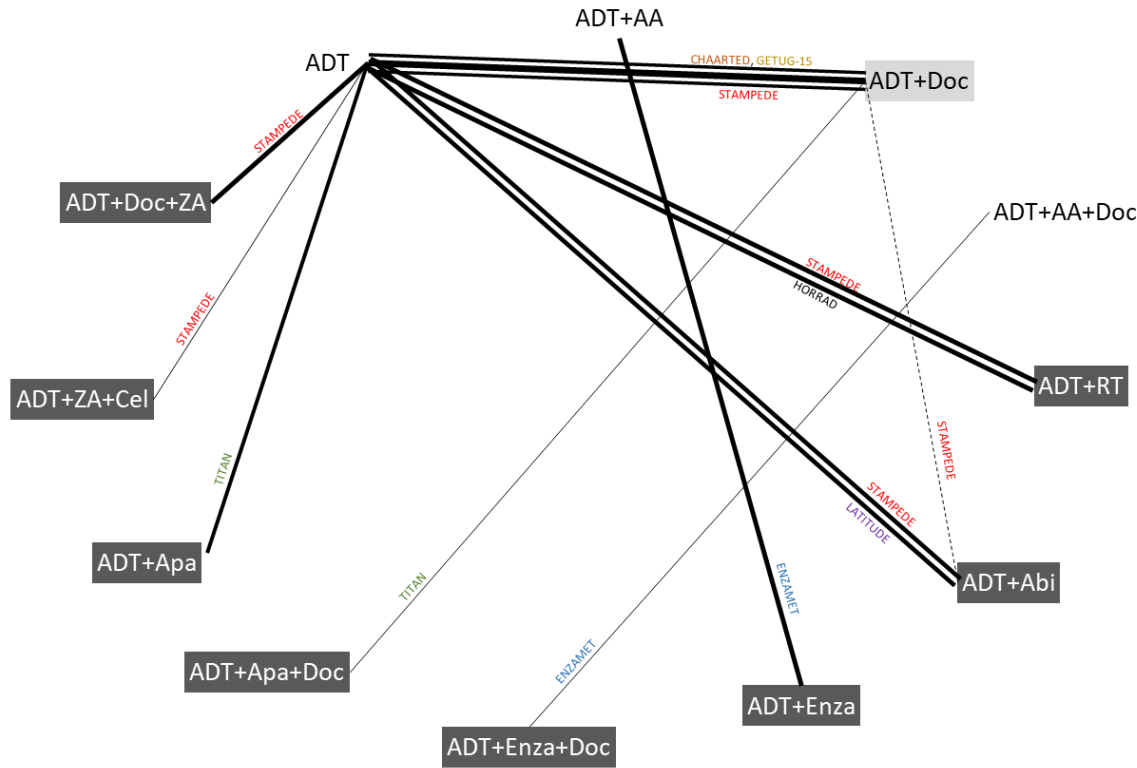
Future networks and interpreting published data

Reported prior therapy and metastatic volume in GETUG-15 and CHAARTED



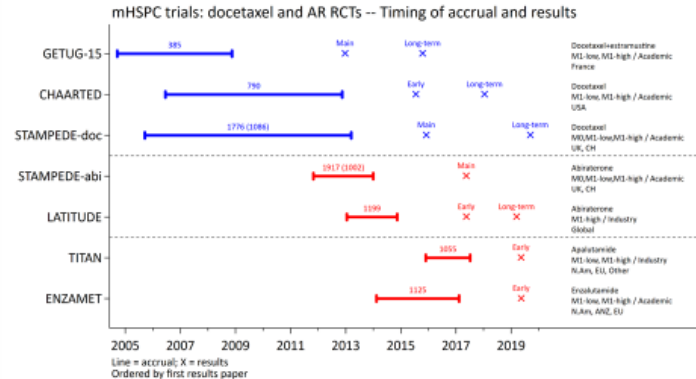
- ‡ Timing to recruitment
(proxy for many things including access to treatment at relapse)
- ‡ Geography of recruitment
- ‡ Use of docetaxel in standard-of-care
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Future networks and interpreting published data

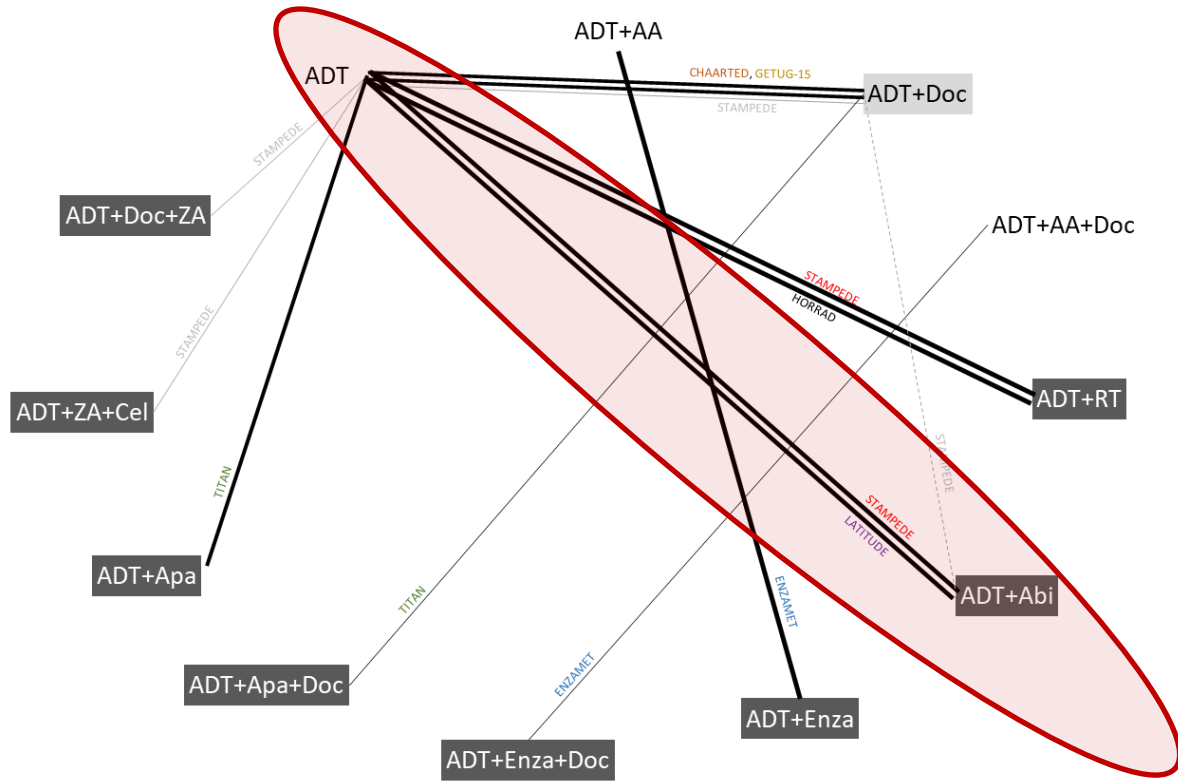


All data

- ‡ Timing to recruitment
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Future networks and interpreting published data - burden

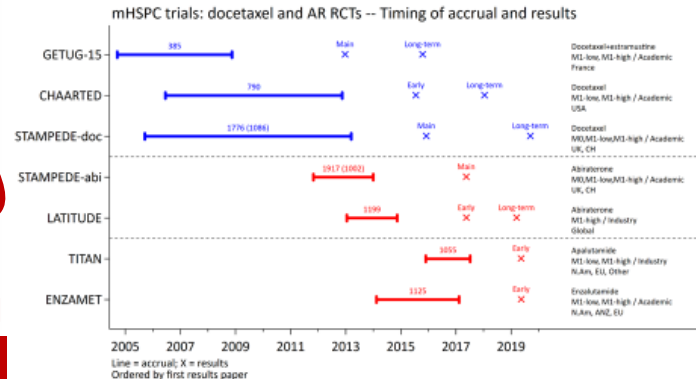


Data available by volume

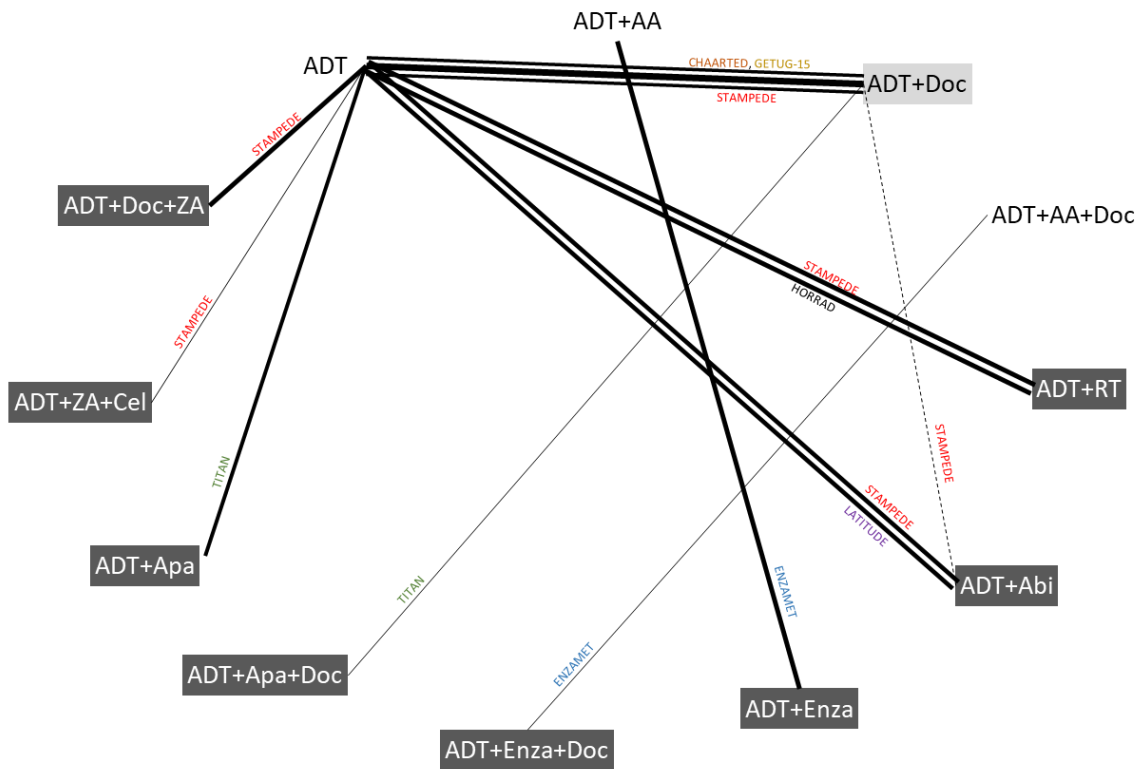
STAMPEDE-abi by volume now online at Eur Urol

doi: 10.1016/j.eururo.2019.08.006

- ‡ Timing to recruitment
(proxy for many things including access to treatment at relapse)
- ‡ Geography of recruitment
- ‡ Use of docetaxel in standard-of-care
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Future networks and interpreting published data – more...

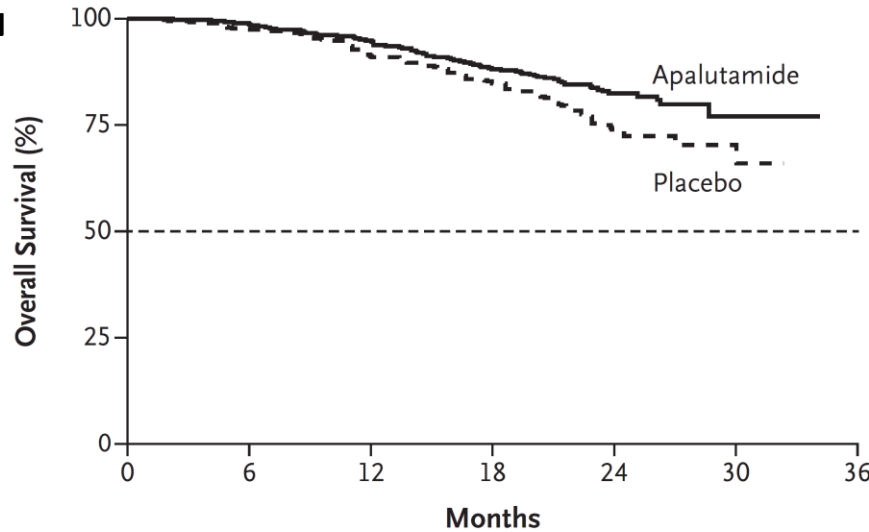


All data

- ‡ Timing to recruitment
(proxy for many things including access to treatment at relapse)
- ‡ Geography of recruitment
- ‡ Use of docetaxel in standard-of-care
- ‡ Use of previous local therapy
- ‡ Use of metastatic volume or burden as stratifier (entry or analyses)
- ‡ Use of AA in control
- ‡ Timing of randomisation
- ‡ Outcome measure definition
- ‡ Timing and method of assessments
- ‡ Timing of reporting
- ‡ Length of follow-up
- ‡ Utility of reporting

Interpreting published data: follow-up and reporting

TITAN



No. at Risk

Apalutamide	525	513	490	410	165	14	0
Placebo	527	509	473	387	142	16	0

No information about
censoring or events

Very very few patients

No patients

	No. of Patients	Median Overall Survival (95% CI) <i>mo</i>
Apalutamide	525	NE
Placebo	527	NE

Hazard ratio for death, 0.67 (95% CI, 0.51–0.89)
P=0.005



KMunicate project: how might we improve Kaplan-Meier graphs?

:: Results of 1,000 person survey
due out shortly

:: Included oncologists, surgeons
& editors

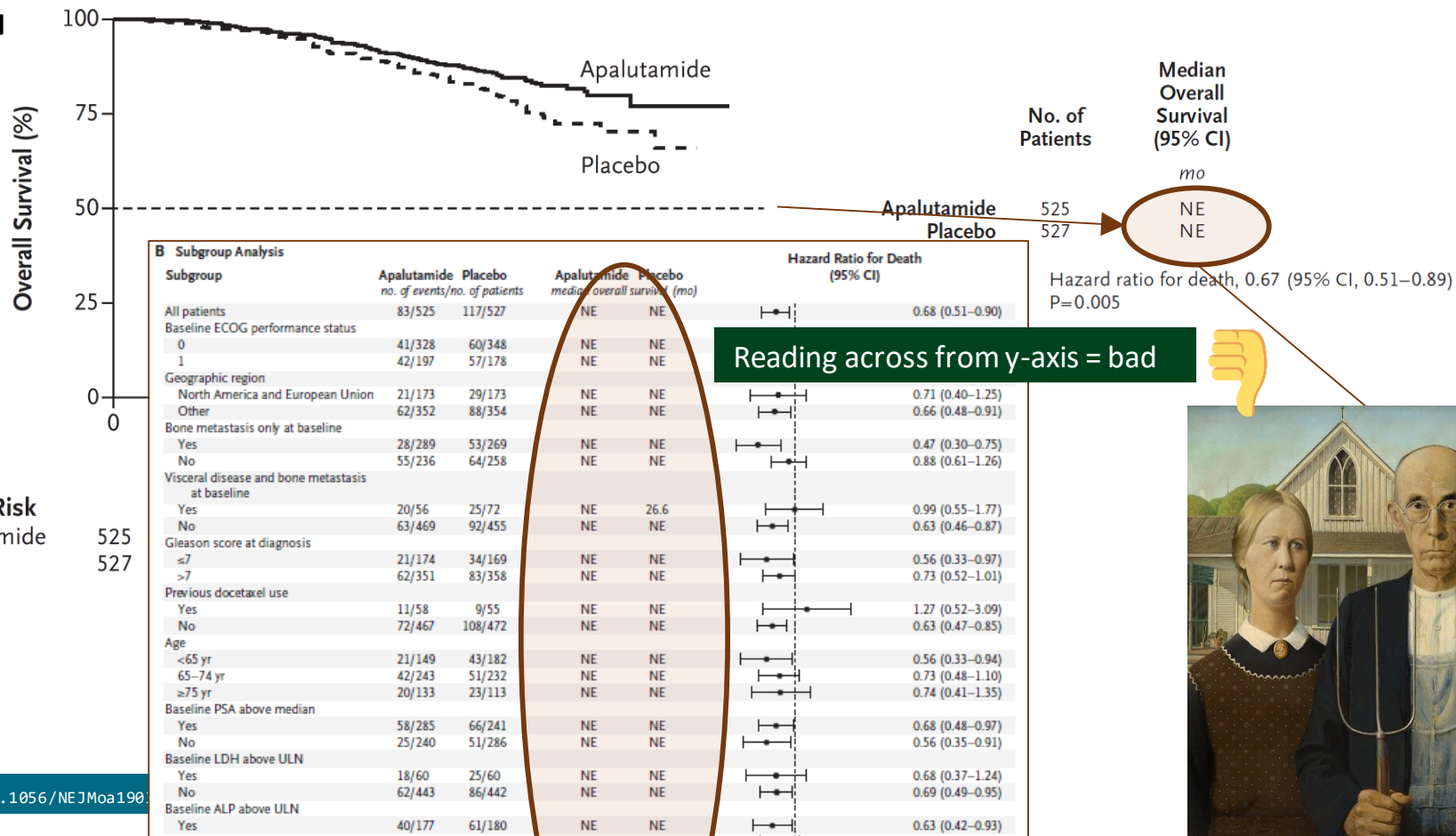
:: Email for results

BMJ Journals

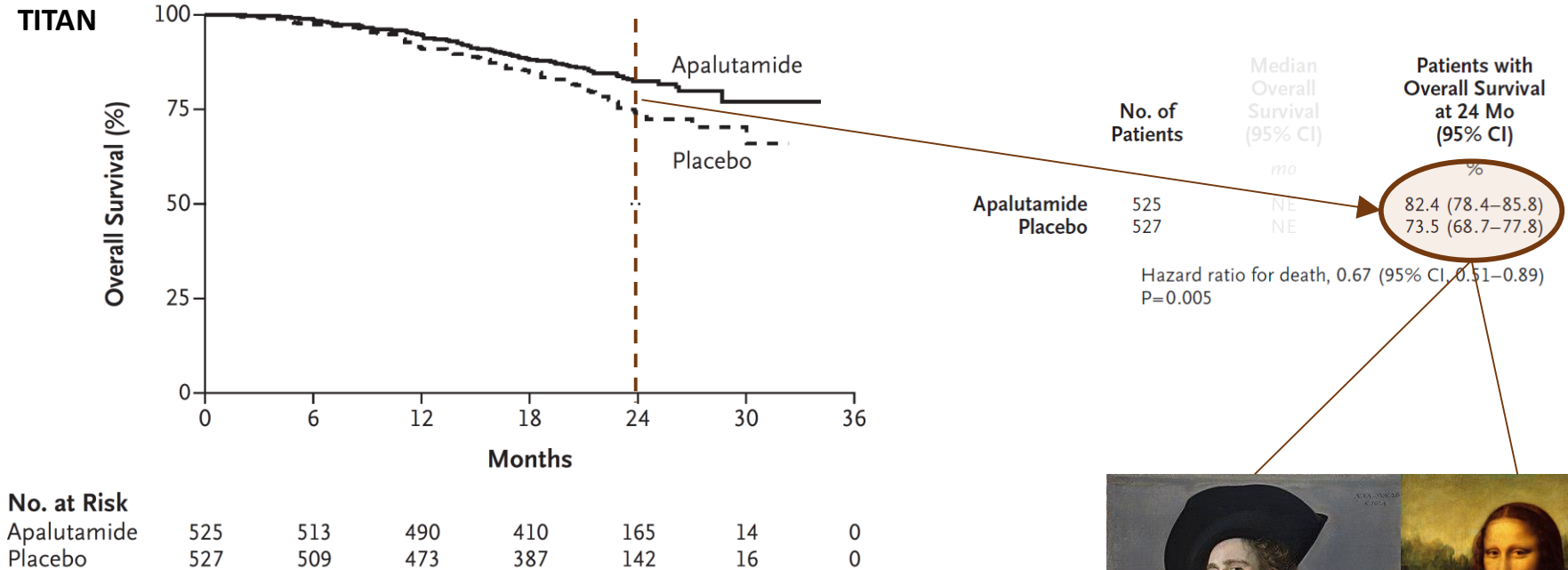
BMJ Open

Interpreting published data: follow-up and reporting

TITAN



Interpreting published data: follow-up and reporting



Reading up from x-axis = good



Need: individual patient data (IPD) network meta-analysis



Speeding up the evaluation of therapies for metastatic hormone-sensitive prostate cancer

Programme Management Group



Jayne Tierney
Professor of Evidence Synthesis



Claire Vale
Senior Research Scientist



Sarah Burdett
Senior Research Scientist



Larysa Rydzewska
Research Scientist



David Fisher
Statistician



Ewelina Rogozinska
Research Scientist

Framework for Adaptive Meta-analysis (FAME)



STOPCAP M1 meeting at ESMO

Jayne Tierney, Max Parmar, Chris Sweeney and Bertrand Tombal would like to invite representatives from key trials, patient groups, charities, funders and industry to attend a STOPCAP M1 meeting during ESMO 2019.

We aim to discuss:

- How we are investigating which treatments work best for which men
- How we are identifying surrogate outcomes for use in future trials
- Implications of recent results for ongoing evaluations and new trials

Friday 27th September 2019
10:30 - 12:00
Room Nélva, Hotel Santos Porta Fira, Barcelona
(close to the congress venue)

More details will follow

If you would like to attend or for more information, please email MRCCTU.STOPCAPM1@ucl.ac.uk



International Advisory Group



Christopher Sweeney
Clinical advisor
Dana-Farber Cancer Institute, Boston, MA, USA



Bertrand Tombal
Clinical advisor
Université catholique de Louvain,
Cliniques universitaires Saint-Luc,
Brussels, Belgium



Mahesh Parmar
Statistical advisor
MRC Clinical Trials Unit and the Institute
of Clinical Trials and Methodology at
University College London, UK

Advert break

ICTMC 2019 – BRIGHTON

6th – 9th October 2019

40
Days

4
Hours

50
Mins

16
Seconds

[View Programme](#)

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Credit: VisitBrighton & Adam Bronkhorst



Event Date

6th - 9th October 2019



Event Location

Brighton UK



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ictmc@in-conference.org.uk

Independent Data Monitoring Committee course

Independent Data Monitoring Committees: a one-day interactive training course

Next course: Tuesday 29th October 2019

Location: 90 High Holborn, London

APPLY NOW

Do you or will you sit on Independent Data Monitoring Committees (IDMC)* or have a trial that needs to be overseen by an IDMC? If so, this popular one-day course is for you, whether you are a clinician, statistician, or work in trial operations.

The multidisciplinary Faculty will lead participants through many of the challenges associated with reviewing accumulating data from clinical trials, and the practical and statistical issues that you need to know when setting up and running an IDMC.

Using lectures, group discussions, and real-life case studies the course will cover:

- Roles and responsibilities of an IDMC
- Membership and the need for independence
- Best practice and decision-making
- Recommendations, decisions, and relationships to other committees

Faculty

The experienced panel is co-chaired by [Prof Max Parmar](#) and [Matt Sydes](#), with [Laura Farrelly](#), and joined by leading trial clinicians drawn from a pool that includes [Jeremy Chataway](#) and [Rick Kaplan](#)

Reviews

This successful course has been running bi-annually since 2015 and attended by clinical fellows, consultants, statisticians many backgrounds from across the UK and Northern Europe. Feedback has been consistently excellent:

“ I really enjoyed the discussions with experts, with plenty of time for questions. Great mix of presentations and group work with very good real-world examples.

Clinical Fellow, MRC CTU, from London, September 2017.

“ Knowledgeable faculty. Enough time for questions.

Clinician from Birmingham.

“ The knowledge of the facilitators (and that they gave up a day of their time made you realise how

Course aimed at:

- new IDMC members
- new CIs
- people likely to be on or report to future IDMCs (clinical, statistical, operational)

Next dates:

29-Oct-2019

+ Spring 2020 (Date TBC)

Booking open at: <https://www.ucl.ac.uk/clinical-trials-and-methodology/education/short-courses/idmc>

~~Advert break~~

CONCLUSIONS

Increasing number of positive trials in mHSPC

Very little direct head-to-head data comparing new treatments

Be cautious in comparing results from papers

Consider:

- characteristics of trials and patients
- all outcome measures, including efficacy and safety
- available and cost of treatments

Help each other with:

- consistent outcome measures and assessments
- clear presentations of results

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Matthew Sydes

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London, UK

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Twitter: [@mattsydes](https://twitter.com/mattsydes)

Email for mailing list for KMunicate results

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