

Launch PragMagic

An innovative tool to assist pragmatic trial design

Rick Grobbee (UMCU)

Iris Goetz (Lilly), Evert Hoogendoorn (IJsfontein)

Mira Zuidgeest (UMCU)

WP3 GetReal

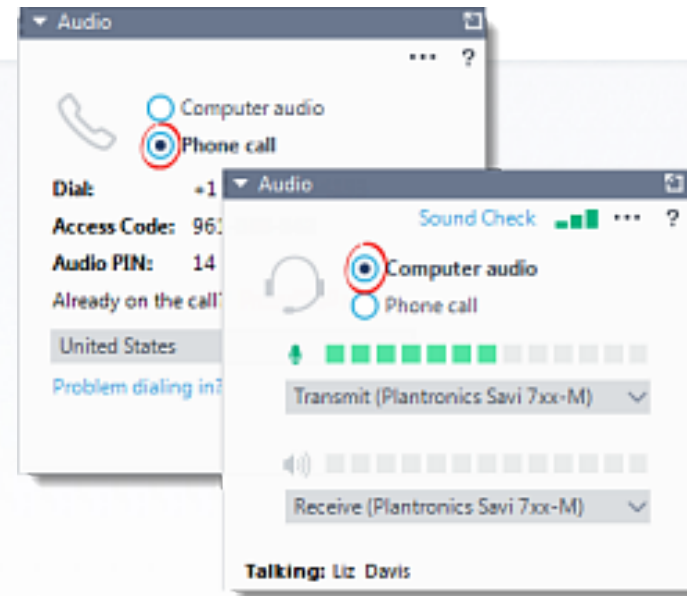


The research leading to these results has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement no [115546], resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.

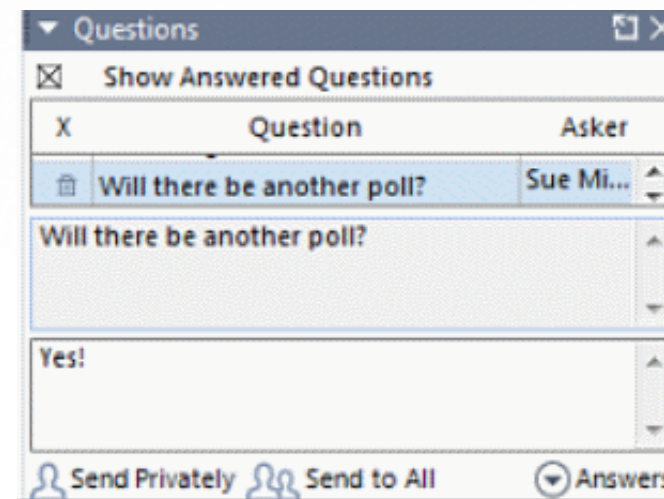
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The final 30 min of the webinar will be for audience Q&A, please use the question bar in the control panel



Speakers



Rick Grobbee
Professor of Clinical
Epidemiology,
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Iris Goetz
Research Advisor
Epidemiology,
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Outcomes,
Eli Lilly



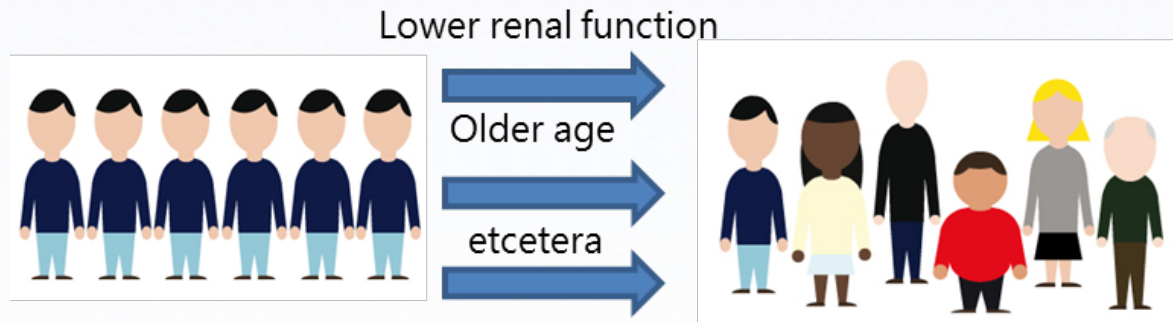
Evert Hoogendoorn
Strategist and
gamedesigner,
IJsfontein



Mira Zuidgeest
Assistant Professor,
University Medical
Center Utrecht

Introduction pragmatic trials

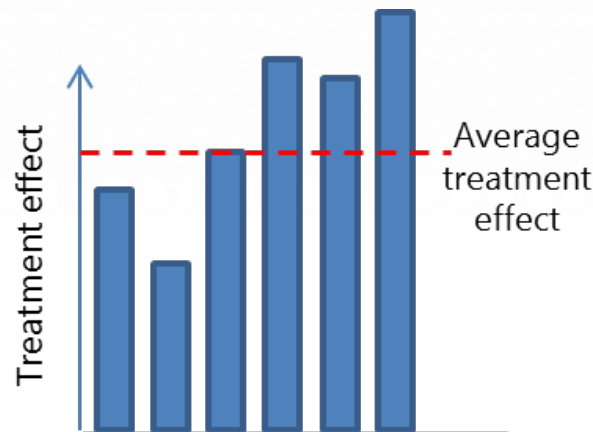
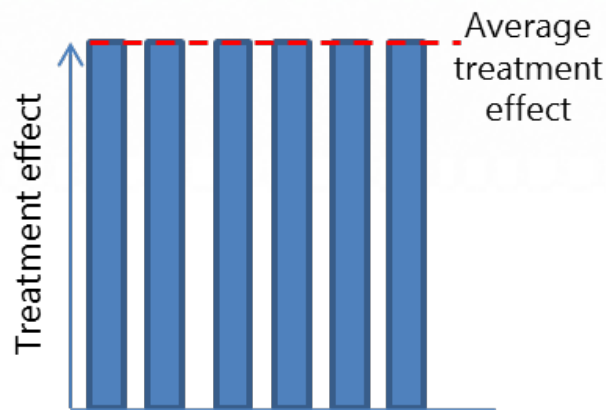
Rick



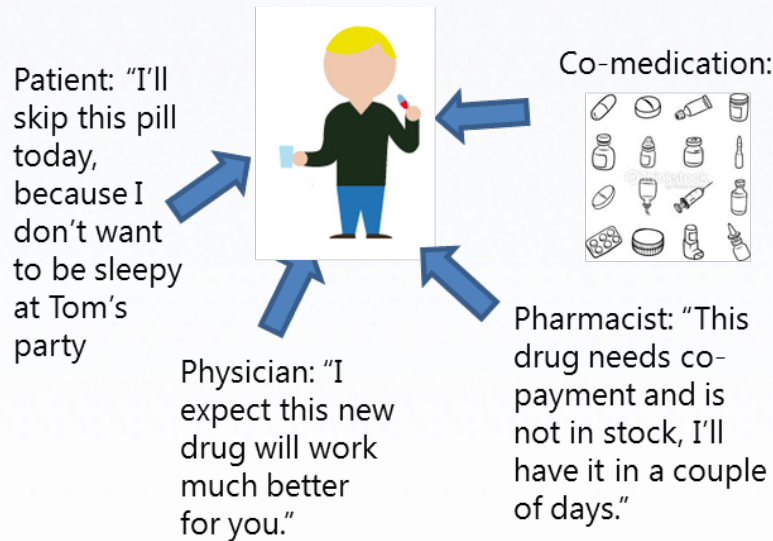
Possible modifiers of drug response



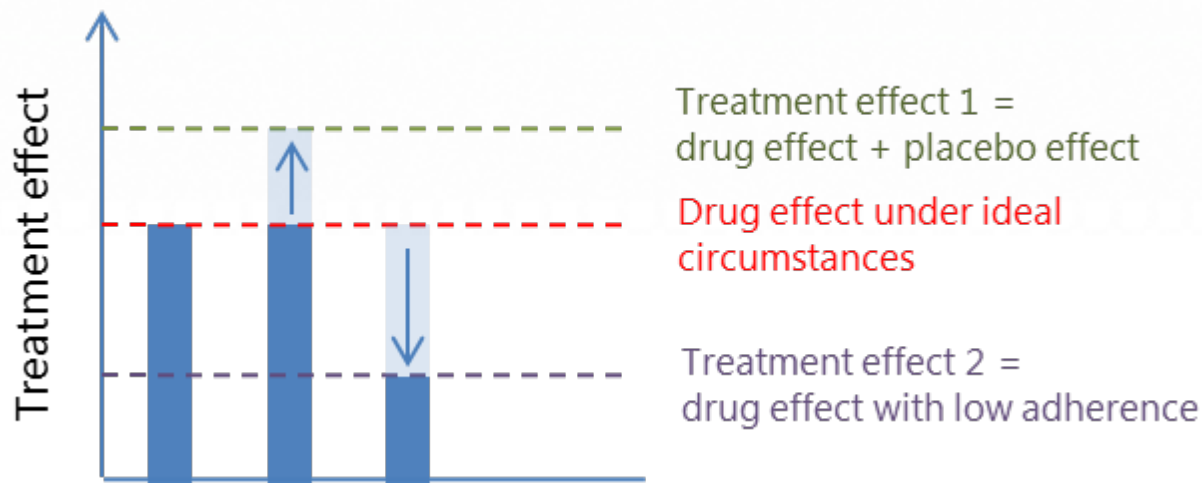
Generalisability of study results to population of interest?



Zuidegeest et al., JCE 2017



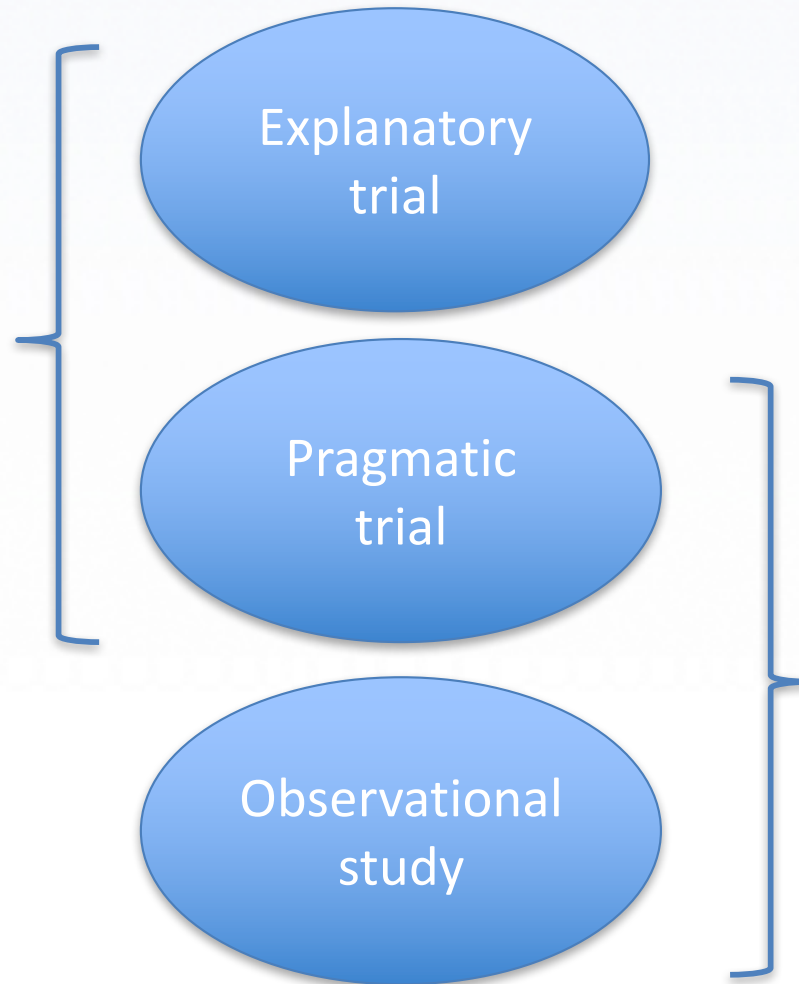
Extraneous factors



Drug effect versus treatment strategy

Zuidegeest et al., JCE 2017

Randomization
=
prognostic comparability between patient groups



Real World Evidence
=
How does treatment strategy A compare to treatment strategy B (often usual care) in daily clinical practice?

Pragmatic trials



Aim:
better guide
physicians
and policy
makers
in choosing
the optimal
treatment

Generalisability
of results to
population and
setting of
interest

Clinically
relevant
comparators and
outcome(s)

Comparison of
treatment
strategies
(drug effect +
extraneous
factors)

Zuidegest et al. Pragmatic trials and real world evidence - an introduction to the series. JCE 2017

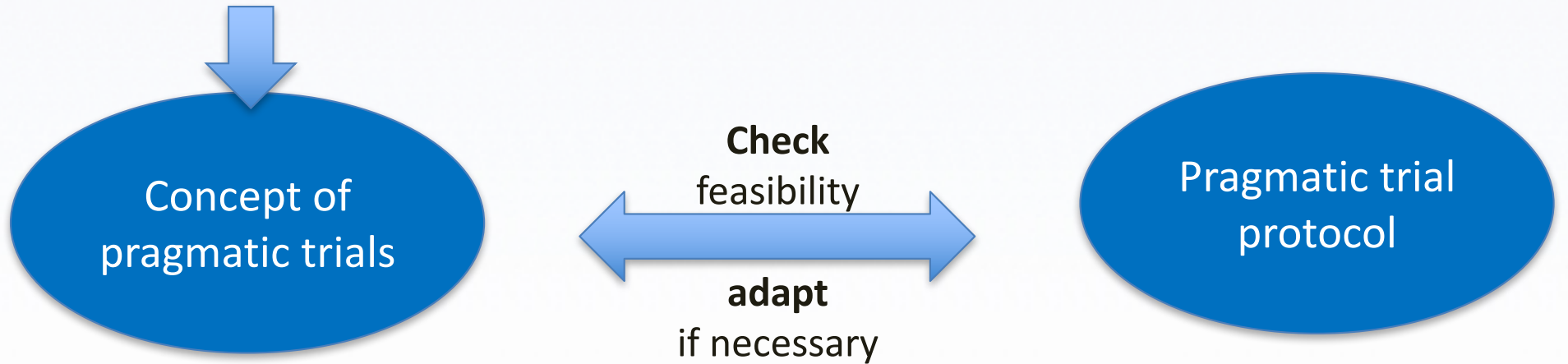
Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutical trials. Journal of chronic diseases. 1967;20:637-48



Pragmatic trials and Operational Challenges: a tool to help you through the maze: PragMagic

Iris Goetz, MD MSc (Lilly)

! RESEARCH QUESTION !



- **Generalisability** to population of interest
- **Treatment strategies** (drug effect + extraneous factors)
- **Clinically relevant**

- **Representative** patients/sites
- **Clinically relevant treatment alternatives** adapted to local context.
- Clinically relevant outcomes measured in usual care
- Minimize impact on routine care

Sites/ Patients

- Identification & selection?
- Site performance – help needed?
- Sample size adequate?

Tx

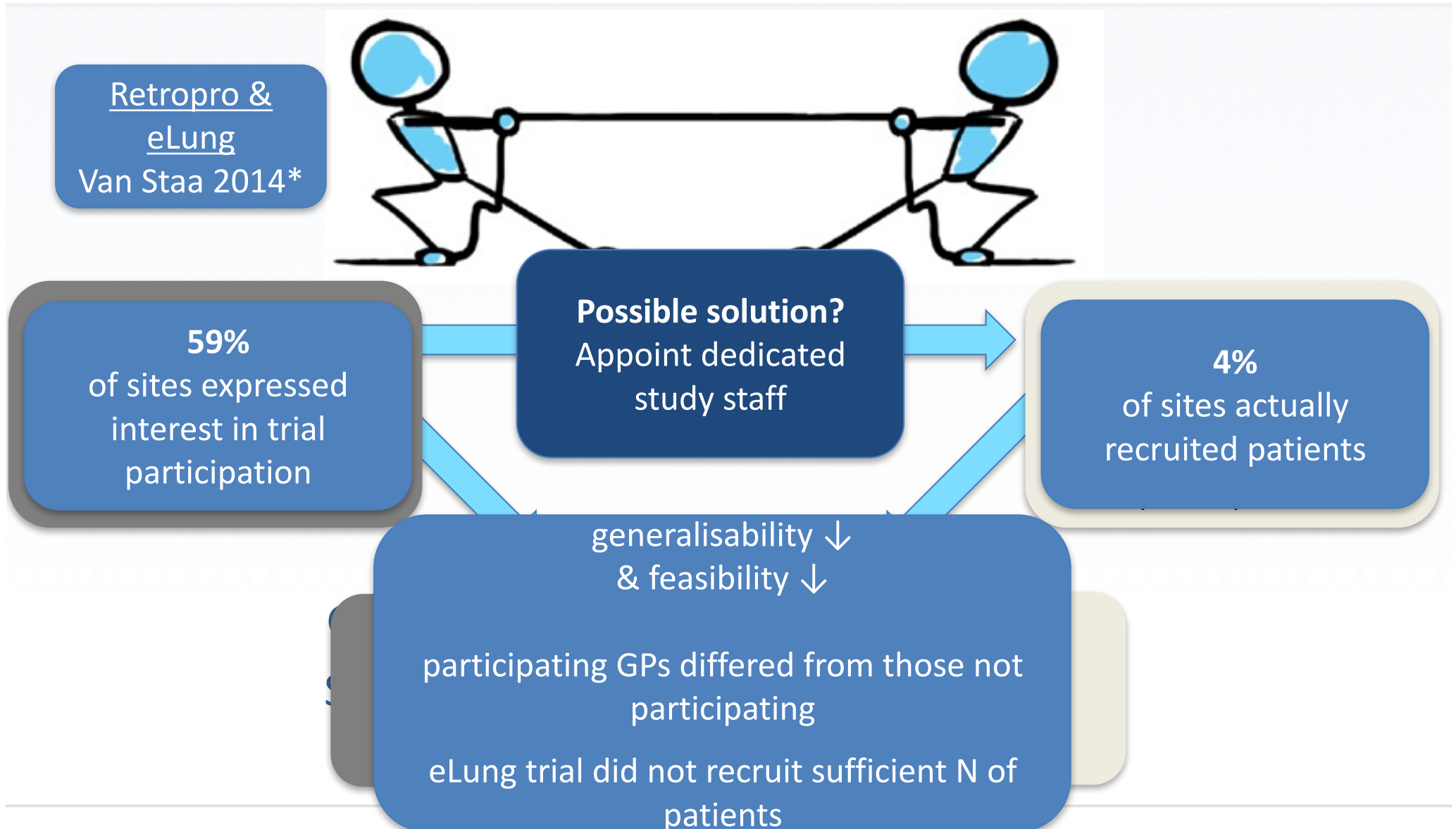
- Definition?
- Variability?

Outcome

- Outcomes usual care?
- Data capture?
- Assessor Blinding feasible?
- Follow-up longer?

Feasibility

- Access to drug ?
- Training & Monitoring?
- Missing Data and post-Randomization bias?



* Van Staa et al. The opportunities and challenges of pragmatic point-of-care randomised trials using routinely collected electronic records: evaluations of two exemplar trials. Health Technol Assess. 2014;18(43);1-146

Why an online tool for pragmatic trials?



Generate real world evidence in the early stages of drug development



Limited experience with pragmatic trials



Unexpected operational challenges

Major challenge



concept



protocol

- methodology
- feasibility
- stakeholder acceptability
- ethical acceptability



PragMagic tool

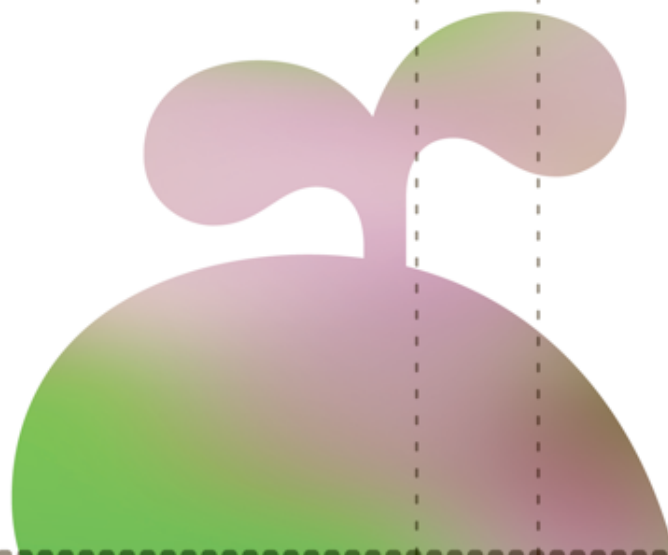
Helps to get familiar with new way of thinking

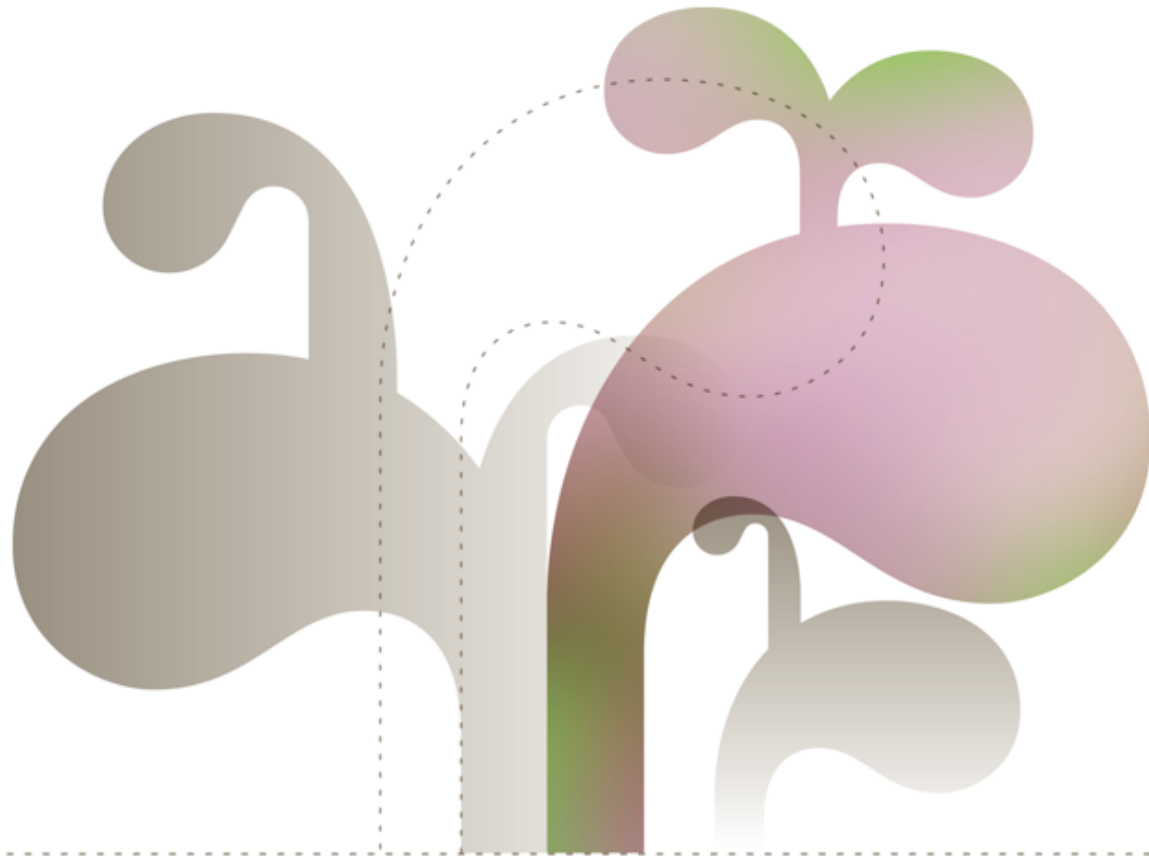
How gaming principles were used to help develop the PragMagic tool

Evert - IJsfontein

ijsfontein

f





Game principles in Pragmatics

rules, behaviour and emotion

Nightboy 9104/9104
70 Druid 7414/10.5k

Dyrendal 17.5k/17.5k
70 Warrior Night Elf 2/100

Lair Brute 17.5k (30%)

group 1

- Radaar 12.7k/12.7k
- Kakuros 11.9k/12.0k
- Marill 10.5k/10.5k
- Miezu 16.5k/18.0k
- Willemtell 10.7k/10.7k

group 2

- Mijat 8681/8681
- Kiccpe 9319/9319
- Chobanne 9121/9121
- Asterion 9033/9033
- Alinutza 8763/8763

group 3

- Unicul 6837/6837
- Invirer 7857/7857
- Hynelinekcz 8183/8183
- Kry 8293/8293
- Nightboy 9104/9104

group 4

- Cicamaca 17.8k/17.8k
- Dyrendal 17.5k/17.5k
- Tamika 12.4k/12.4k
- Kaball
- Dispelator
- Bloodrage - Dyrendal
- Regrowth - Dyrendal

group 5

- Leviethan 7181/7439
- Warshanus 10.4k/10.4k
- Arhizek 17.7k/17.7k
- Saintseraph 8711/8711
- Kypucyka 10.6k/10.6k

BUFFS & TRACKING

- Devotion Aura VIII
- Heroic Presence
- Tree of Life
- Tree of Life
- Prayer of Fortitude III 56:31
- Prayer of Spirit II 55:01
- Gift of the Wild III 54:55
- Arcane Brilliance II 54:01
- Greater Blessing of Kings 26:01
- Omen of Clarity 24:59
- Greater Blessing of Wis... 24:11

DEBUFFS

- Blessing of Demonstration 13:37
- Blessing of Demonstration

Name	Threat	%Max	TPS
Alinutza	40.5k	100	600
Dyrendal	38.0k	94	588
Dispelator	38.0k	94	690
Kypucyka	35.7k	88	857
Miezu	32.4k	80	522
Asterion	31.9k	79	1145
Arhizek	28.0k	69	510
Willemtell	27.8k	69	482
Chobanne	27.3k	68	485
Nightboy	19.7k	49	482

- 3.2 Lifebloom - Dyrendal
- 5.8 Rejuvenation - Dyrendal
- 11 Regrowth - Dyrendal

Kaku	Allin	Hyne	Cica	Arhi	11
Mari	Aste	Invi	Disp	Kypu	5.9
Miez	Chob	Kry	Dyre	Levi	3.4
Rada	Kicc	Nigh	Kaba	Sain	
Will	Mija	Unic	Tami	Wars	

	R	S	X
Gronn-Priest	101010		
Saintseraph	27348		
Kiccpe	26004		
Nightboy	22532		
Leviethan	17172		
Mijat	15917		
Miezu	12426		
Unicul	11853		
Arhizek	5995		
Invirer	5196		
Dyrendal	4999		
Cicamaca	2688		

Warshanus
Fear Soul
Level 70 Gnome Warlock (Player)
PvP

86 12 Cenarion Expedition 16014 / 21000

Game UX is about:

- make the user feel in control
 - give the user a clear goal
 - give the user constant feedback
 - allow multiple strategies
-

Key

Light Green

Pink

Red

Purple

Blue

Dashed Line

One Sided Infatuation (determined by arrow)

Flirtation by both parties

Single date / Kissed / One night Stand

Dated several times or for a short period

Serious Relationship or Marriage

signifies one of the parties is from an alternative reality



Three kinds of behaviour triggered by being lost:





- give up and quit
 - focus on small details and ignore the big picture
 - get it over with as fast as possible
-



Name of trial
email@something.nl

FRAGMENTS

ILLUMINATE THE CITY 





-  Most optimal
-  Opportunity for improvement
-  More opportunity for improvement
-  No implication

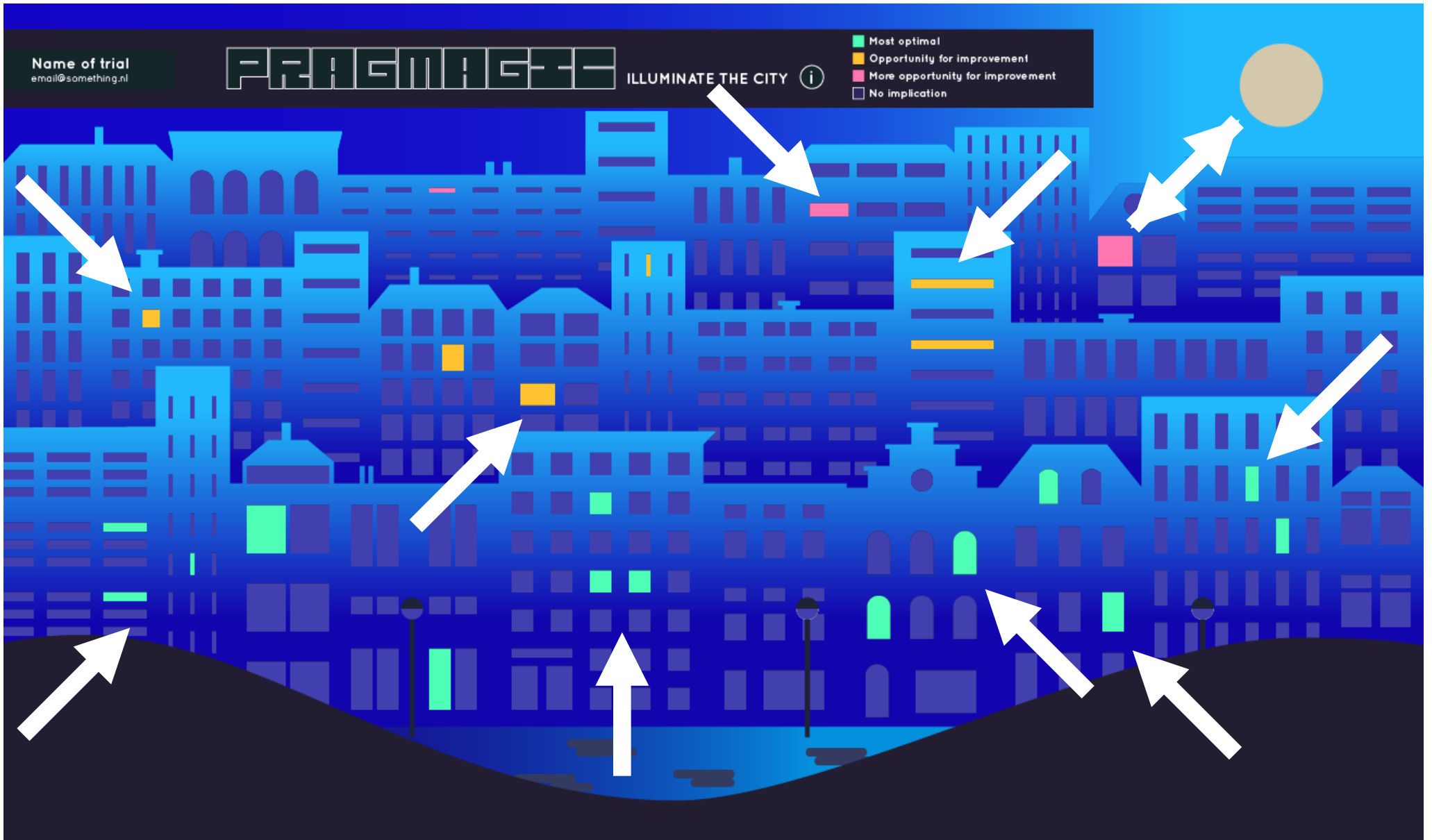


Name of trial
email@something.nl

FRAGMENTEE

ILLUMINATE THE CITY 





-  Most optimal
-  Opportunity for improvement
-  More opportunity for improvement
-  No implication



Name of trial
email@something.nl

FRAGMENT

ILLUMINATE THE CITY 

-  Most optimal
-  Opportunity for improvement
-  More opportunity for improvement
-  No implication



Name of trial
email@something.nl

FRAGMENT

ILLUMINATE THE CITY ⓘ

- Most optimal
- Opportunity for improvement
- More opportunity for improvement
- No implication



Total
55%



2 Operational challenges



2 Notes

Demo PragMagic

Mira Zuidgeest



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ReLIT
info@pragmagic.eu

PRAGMAGIC ILLUMINATE THE CITY

- Optimal
- Opportunity for Improvement
- More opportunity for Improvement
- No Impact

Save
Exit
Export

Demo PragMagic

Progress 49%

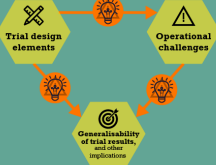
15 Operational challenges 0 Notes

Quality Participant Site Outcome Comparator Data Safety


WWW.PRAGMAGIC.EU




Aim:
 facilitate the design and planning of more pragmatic trials


How:
 giving insights into the consequences of design choices and operational challenges


Result:
 maximise the generalisability of findings while ensuring validity and feasibility

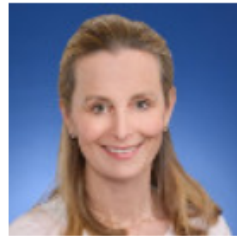

Focus:
 randomised pragmatic trials with a drug component


It is NOT:
 - a decision making tool
 - checklist to assure compliance
 - quality verdict

QUESTIONS?



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