The STROBE statement Amendment proposals

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STROBE

STrengthening the **R**eporting of
OBservational studies in **E**pidemiology [1, 2]

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- Particular issues arise in analysing data from follow-up based on registers:
  - Person follow-up in continuous time
    (all dates known)
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- . . . as opposed to detailed clinical data collected at visits to clinics/doctors.

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- Implies that we should look at follow-up in small pieces
  — in the limit at every single time of follow up.

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- **STROBE:** Already a note on informative loss to follow-up.
  "State clearly if persons are excluded from follow-up prior to death or end of follow-up."

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- An ideal specification of relevant determinants

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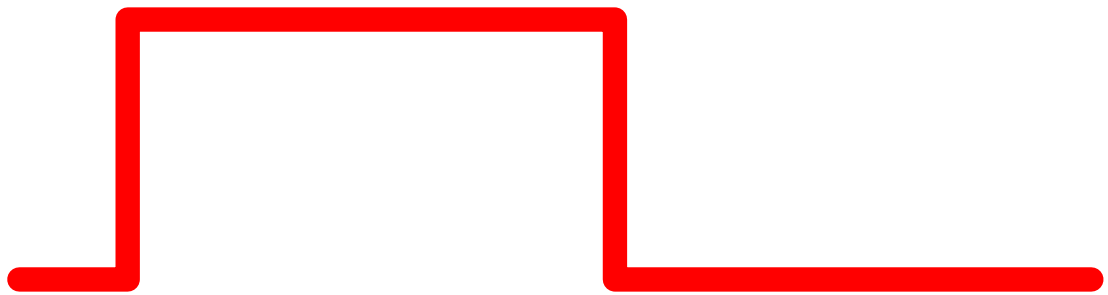
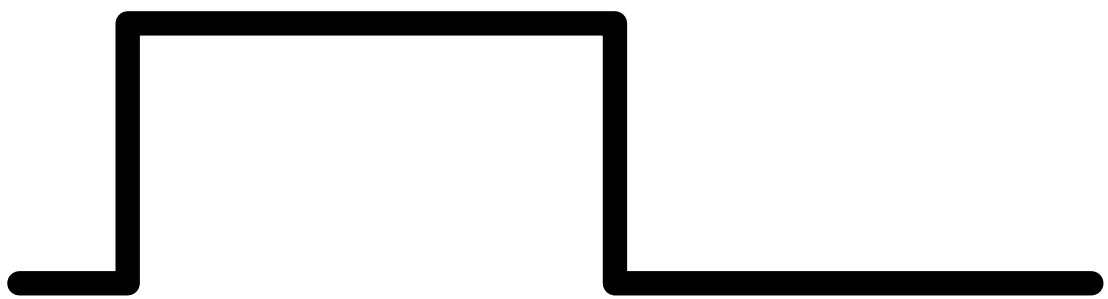
  - Risk of outcome increases immediately at drug start
  - Risk decreases to precisely the previous level at drug cessation



"Drug effect"



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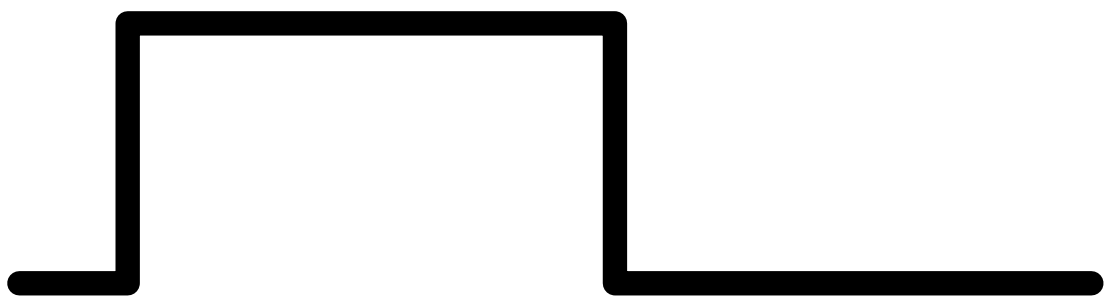

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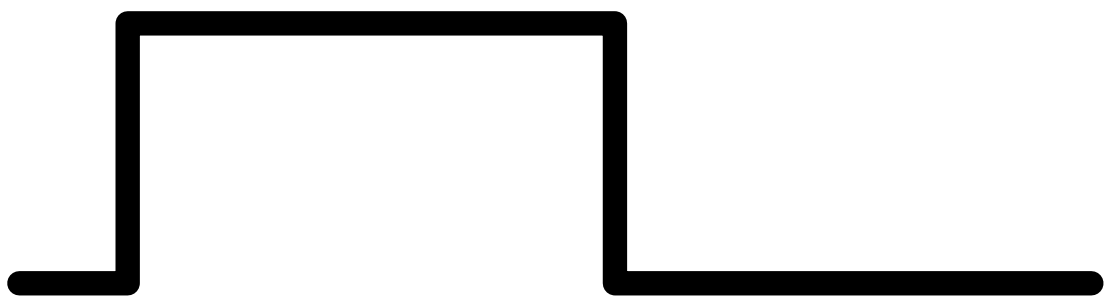

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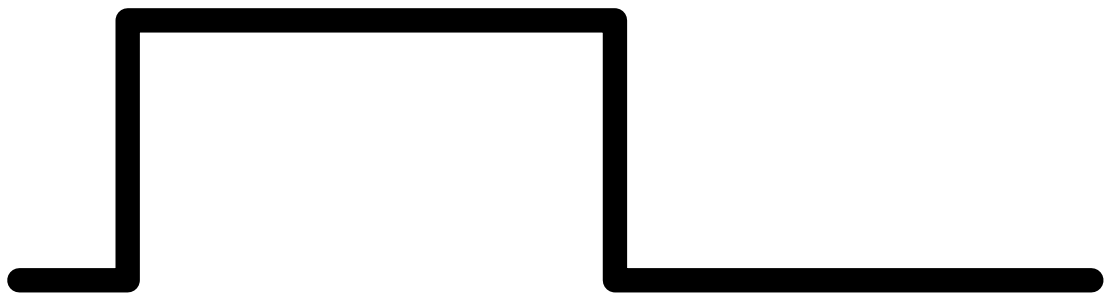
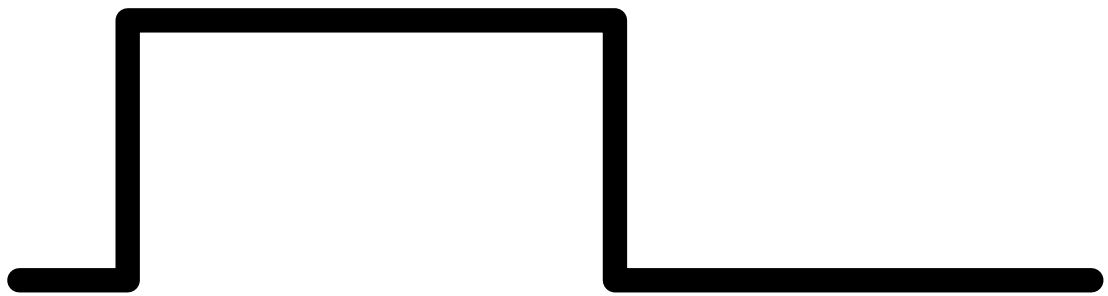


Drug exposure

Indication effect



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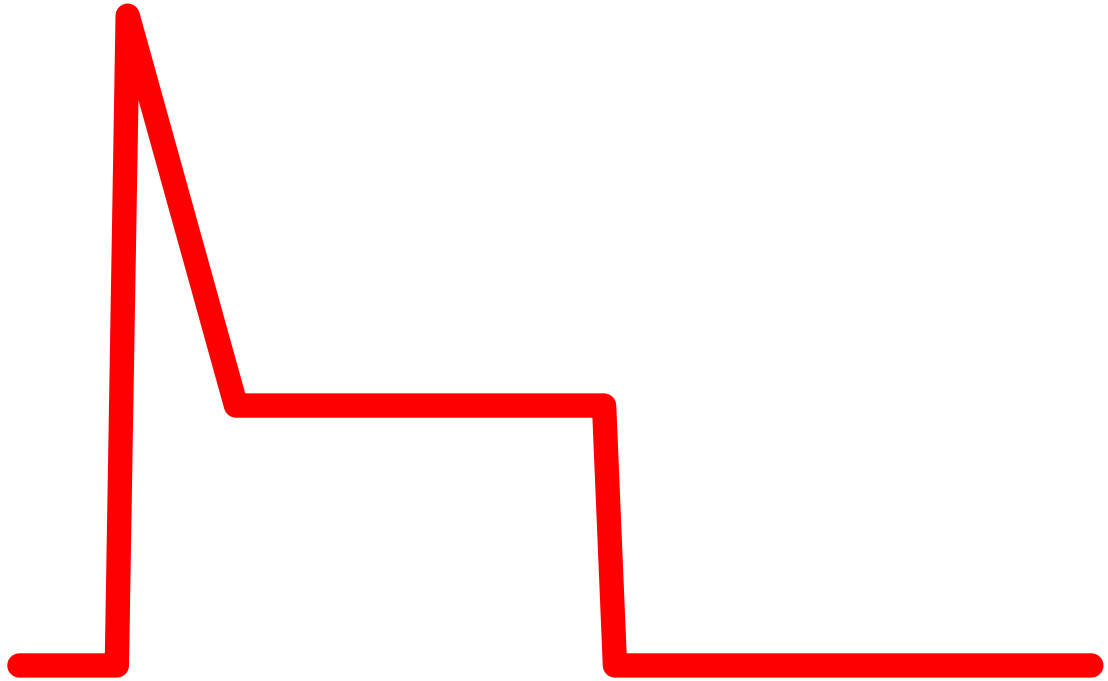

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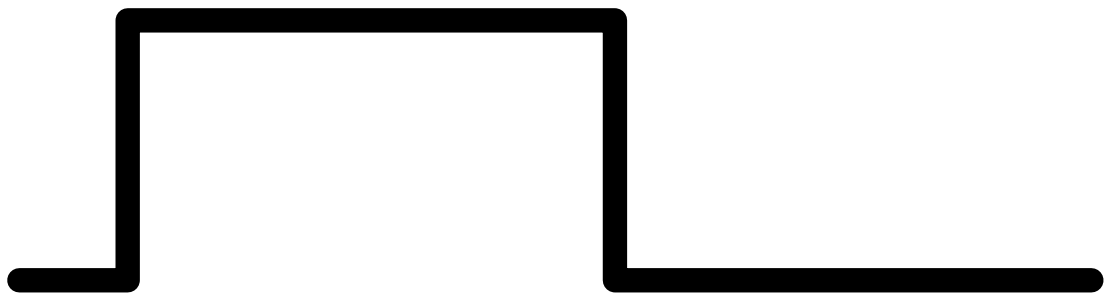

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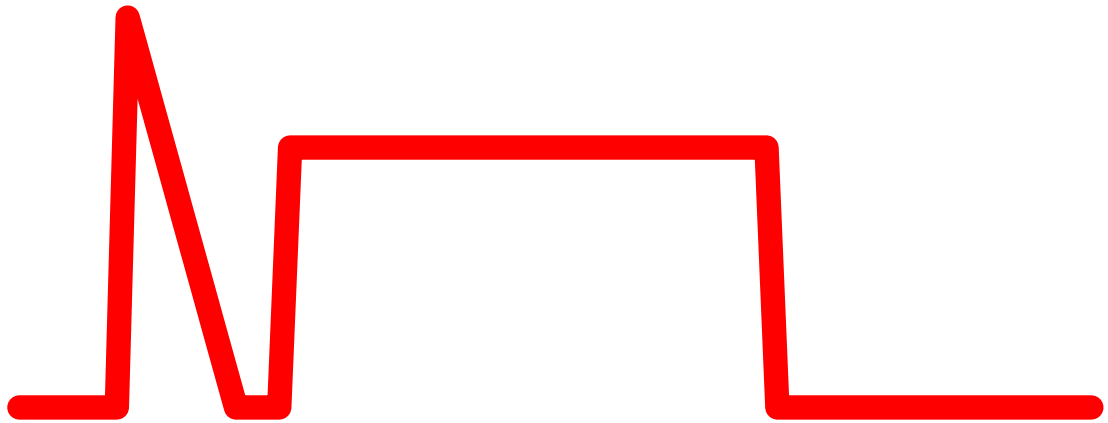

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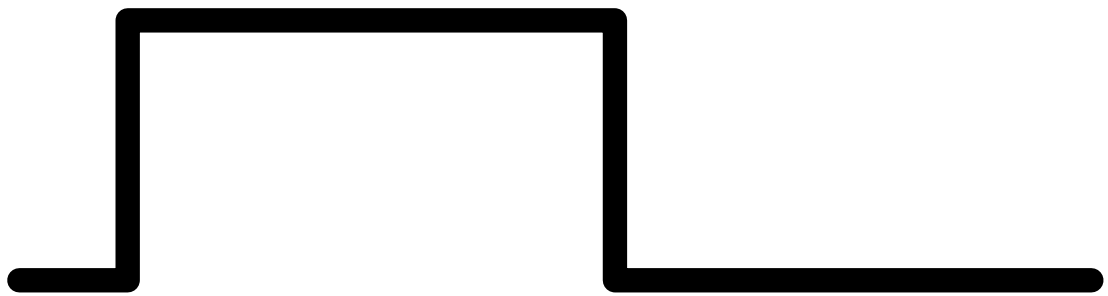

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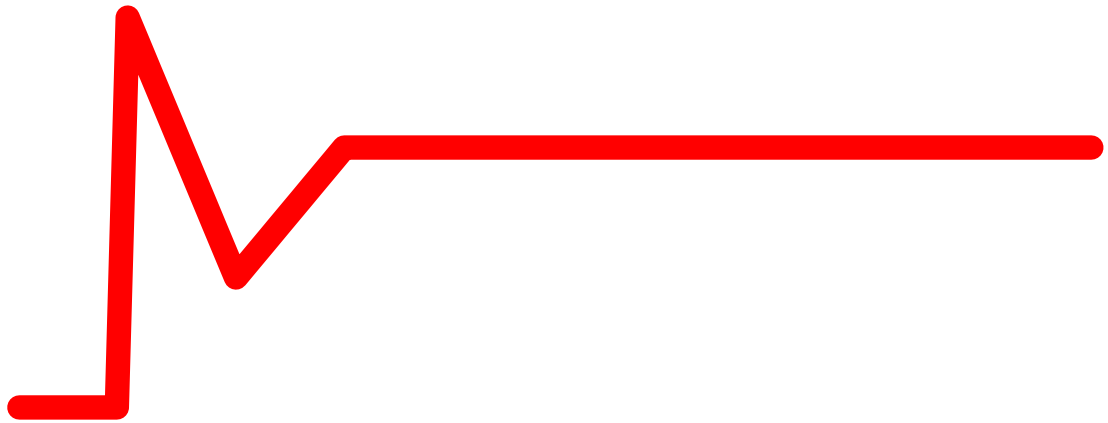

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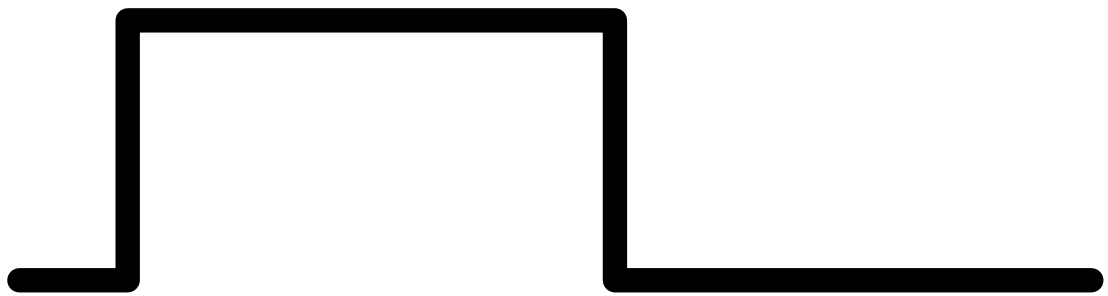

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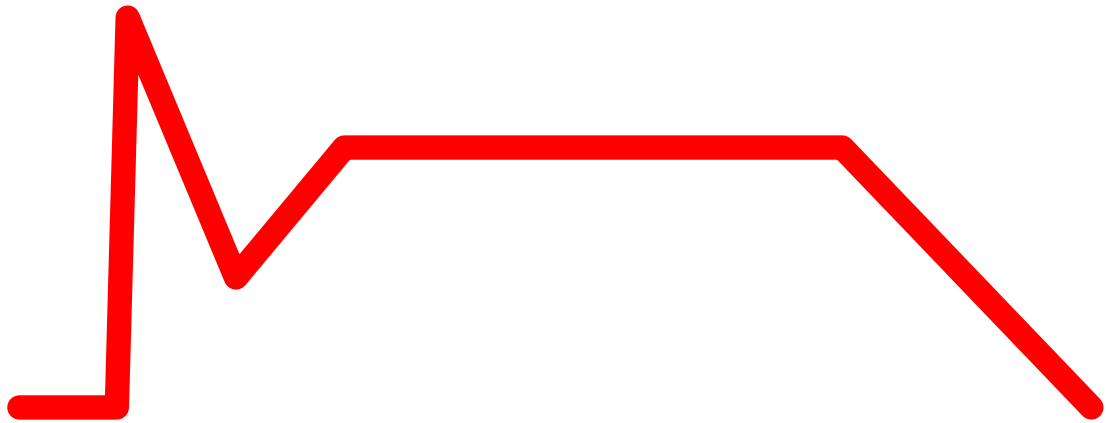

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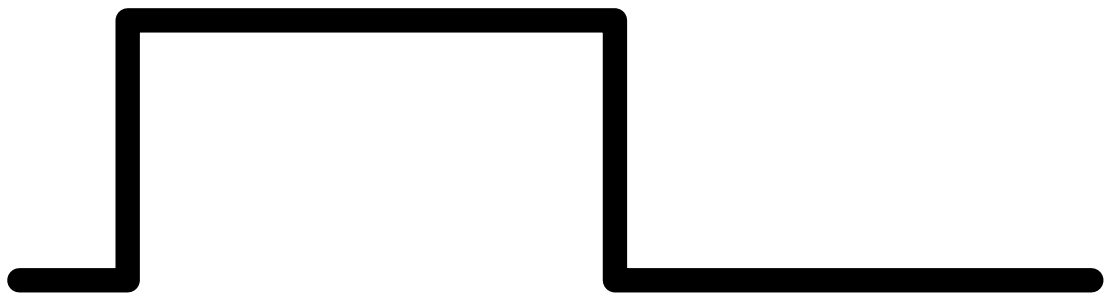

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- We assumed that initiation of XX caused an immediate increase in rates of cancer which remained constant, and only were present for the duration of drug exposure.

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- Drug exposure in a data base is not only (an approximate) measurement of drug exposure, but also of processes around it — indication effects.

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- Rates controlled for... is most often really Rates in a population with a covariate distribution as our study population....

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- The effect of a covariate assuming that all other are fixed.

So what is relevant for STROBE?

- Data base (why are data actually recorded in the first place)
- Data accuracy (exact date of purchase, date of cancer diagnosis only by month,. . .)
- Data rounding (drug exposure only computed every 3 or 6 months)
- Covariate definition at each point of follow-up
- Model assumptions about effects

Proposals for STROBE?

- "State clearly if persons are excluded from follow-up prior to death or end of follow-up."
- "State the aims of covariate definition (exposure) independent of the data available, preferably based on a biological / clinical hypothesis"
- "Explain precisely how the anticipated temporal relationship between drug exposure and effect is modeled."
- "If absolute quantities (rates, risk, ...) are given, state the covariate values (or distribution of such) for which these are computed."

References

J. P. Vandenbroucke, E. von Elm, D. G. Altman, P. C. Goetzsche, C. D. Mulrow, S. J. Pocock, C. Poole, J. J. Schlesselman, and M. Egger.
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