Analytic Challenges from the STOP CRC Trial: Pragmatic Solutions for Pragmatic Problems

William M Vollmer, PhD

April 24, 2015

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Overview

- A number of issues related to implementation of the STOP CRC study have raised questions about the appropriateness of our originally proposed analysis plan

- We would like to review those issues and get your feedback on some proposed analytic solutions

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Strategies and Opportunities to STOP Colorectal Cancer in Priority Populations: the STOP CRC Study

Gloria Coronado, KPCHR, Portland, OR

Beverly Green, GHRI, Seattle, WA

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STOP CRC Primary Objective

Test the effectiveness of automated EMR-driven strategies to raise CRC screening rates in safety-net clinics

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STOP CRC Design

- Cluster randomized trial

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  - Intervention delivered at clinic level

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- 26 federally qualified health clinics that are part of OCHIN network

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STOP CRC Design

- Cluster randomized trial
  - Intervention delivered at clinic level
- 26 federally qualified health clinics that are part of OCHIN network
- EMR used to drive system-level intervention

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STOP CRC Intervention - 1

- OCHIN uses EMR to:
  - Identify individuals eligible for screening per USPSTF guidelines
  - Confirm still an active clinic patient (visit w/i past 12 months)
  - Update list on an ongoing basis over time
  - Make real-time reports available to clinics via a customized report in Reporting Workbench

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  - Update list on an ongoing basis over time
  - Make real-time reports available to clinics via a customized report in Reporting Workbench
- Identify comparable population for usual care clinics
- Recruitment continues for 1 yr for main analysis

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STOP CRC Intervention - 2

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- Clinics “work” their lists in whatever manner best fits with their internal workflows

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STOP CRC Intervention - 2

- Clinics “work” their lists in whatever manner best fits with their internal workflows
- Actual “intervention” consists of prescribed sequence of proactive outreach efforts, including mailed FIT kits

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STOP CRC Outcome

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STOP CRC Outcome

Individual level

- Completion of FIT kit within 12 months of becoming screen eligible

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STOP CRC Outcome

Individual level

- Completion of FIT kit within 12 months of becoming screen eligible

Clinic level

- % targeted patients who complete a FIT kit

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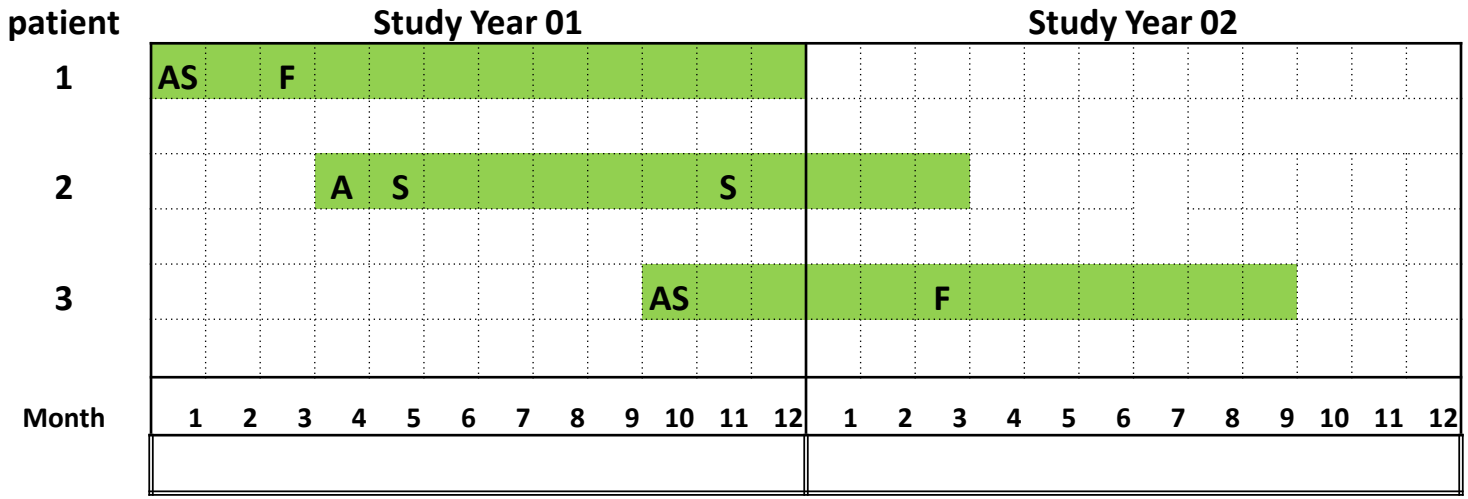
Accrual of Intervention Clinic Patients



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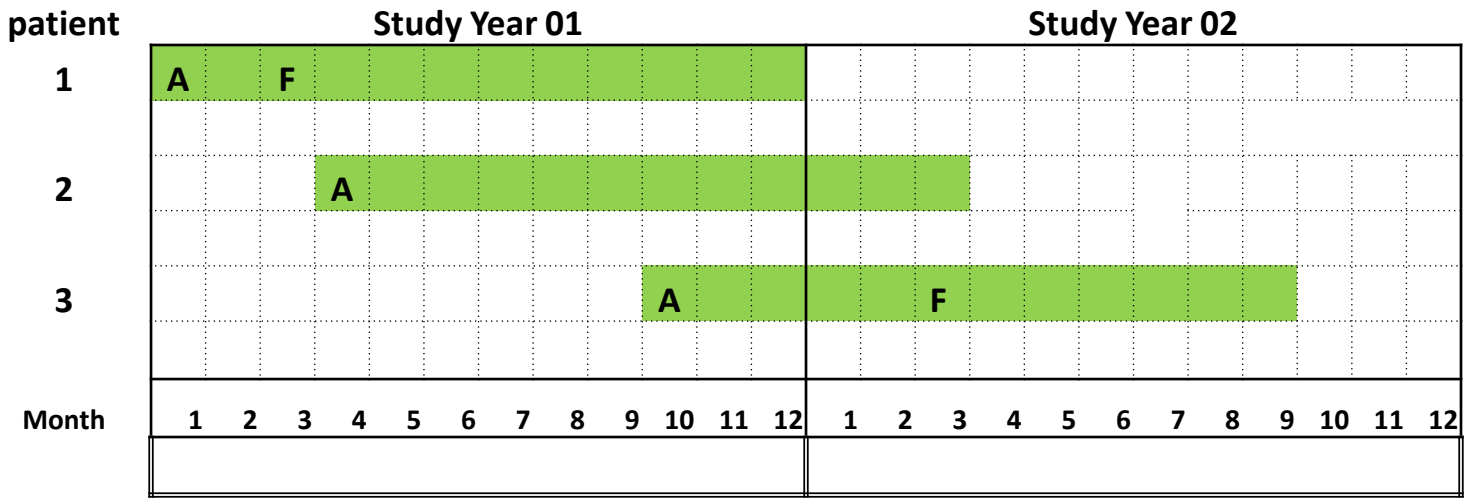

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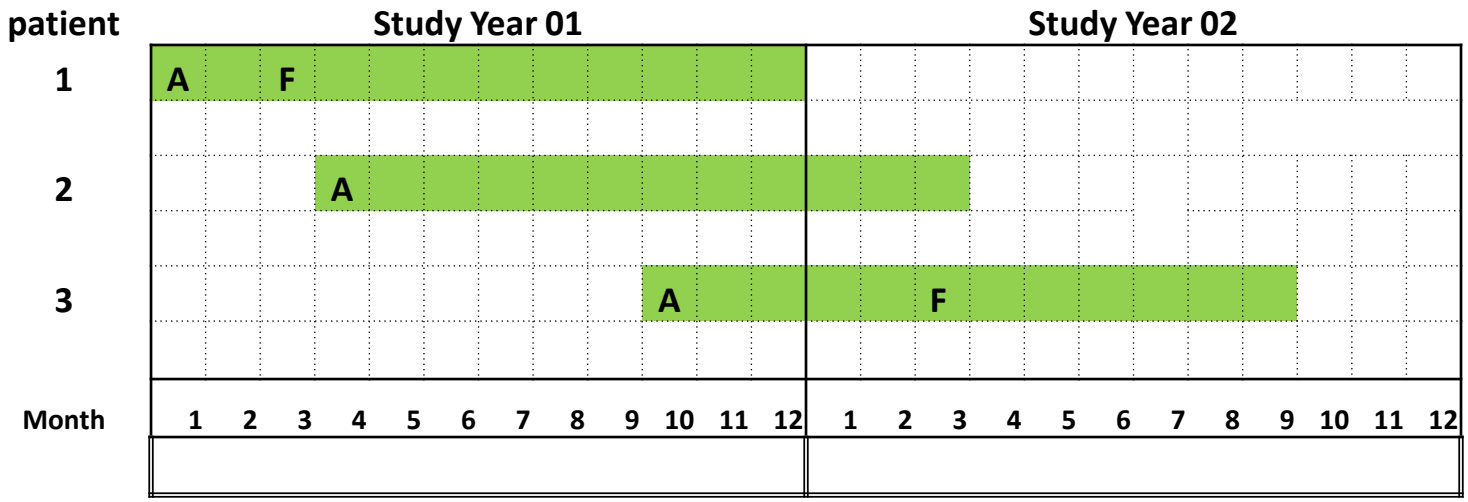

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Overview of Analytic Issues

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Overview of Analytic Issues

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- Use of real-time EMR tools that may be discordant with our static randomization tables
- Implementation delays and ACA rollout
- Conceptualization of year 2 analysis sample

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Analytic Issue #1: Year 2 Intv Rollout

- Control clinics will receive intervention in year 2, yet year 1 measurement window extends into year 2 for many individuals

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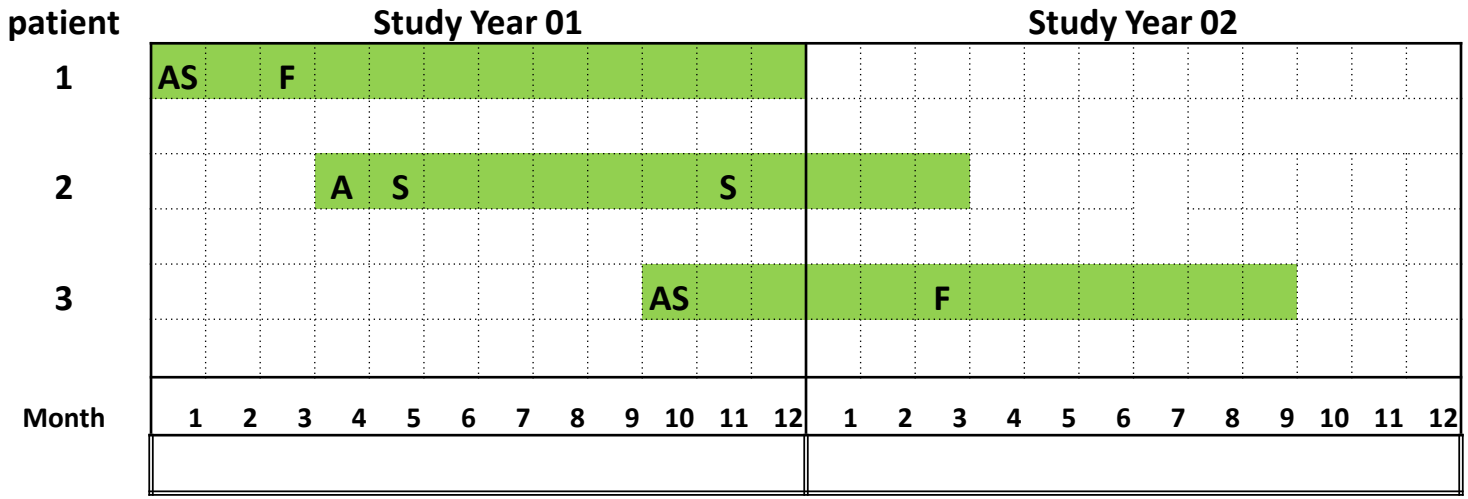

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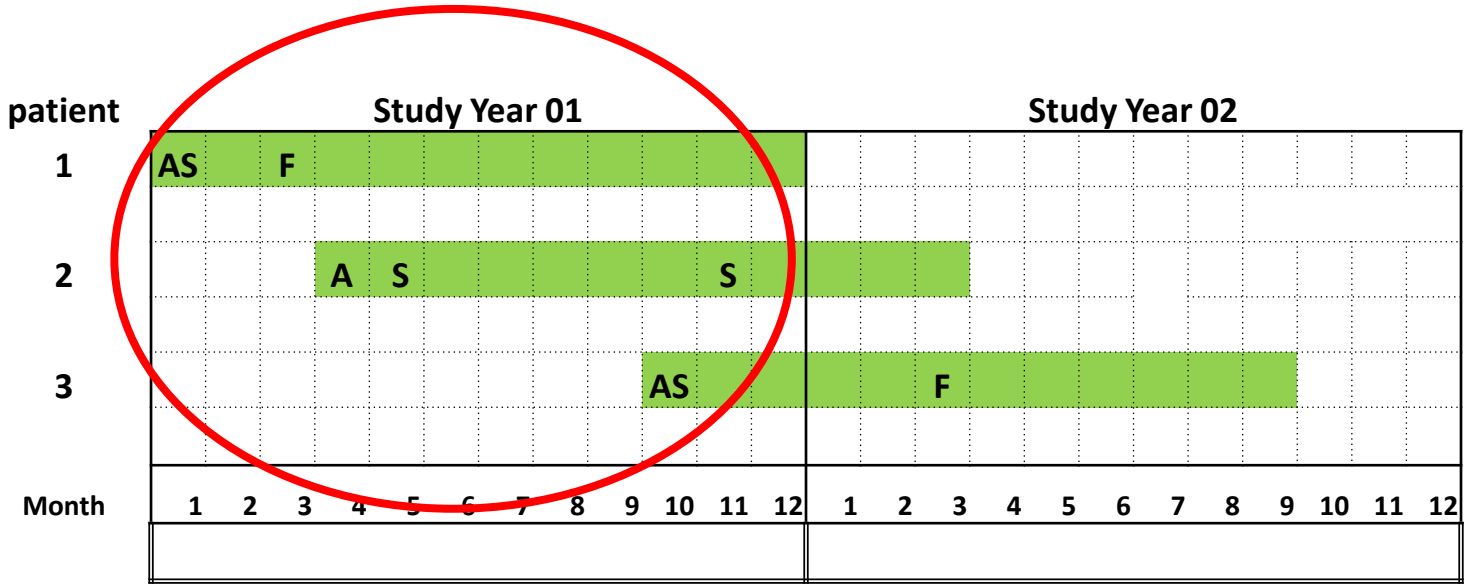

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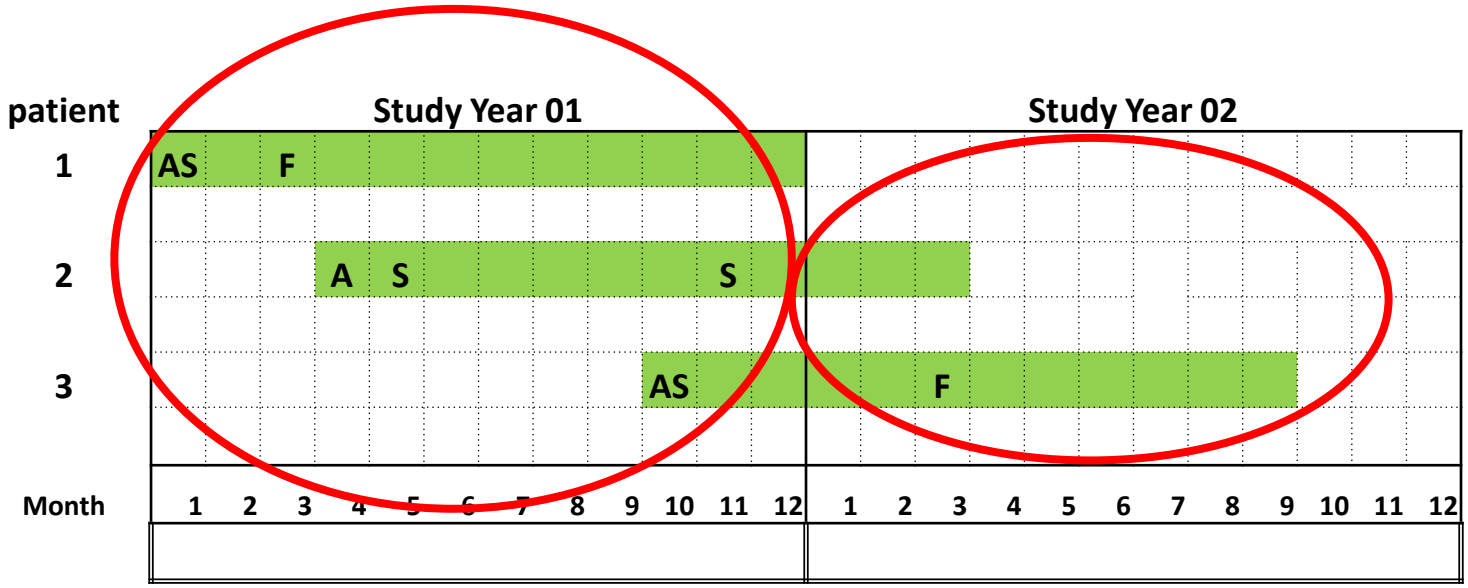

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Impact:

- Year 2 intervention rollout window overlaps year 1 measurement window for some control subjects

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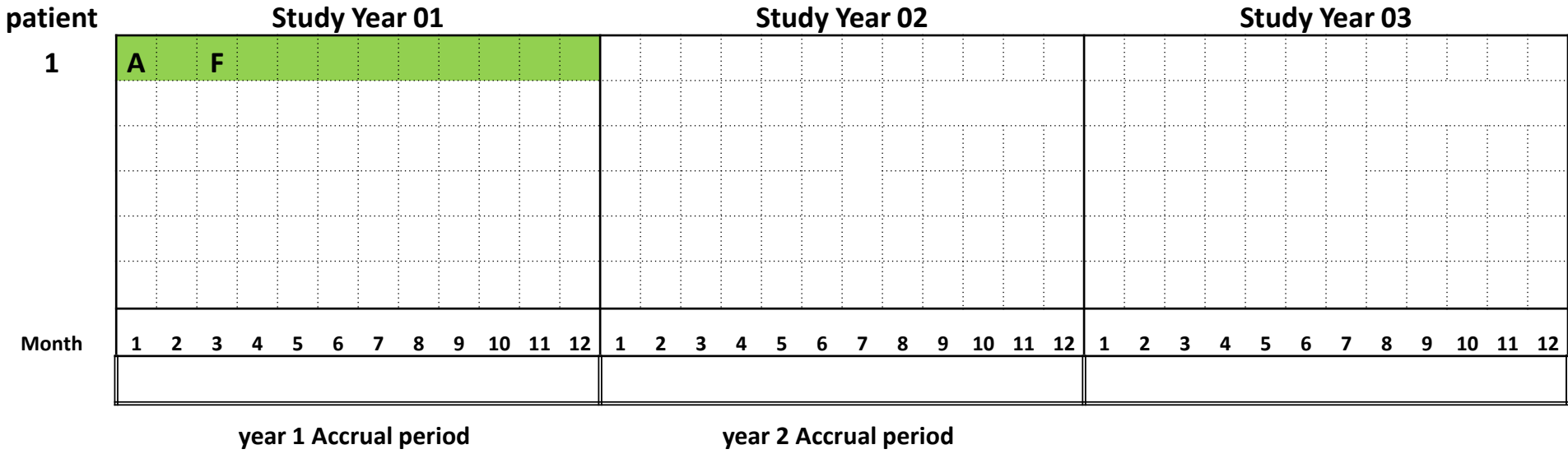
Year 2 Rollout for Control Clinic Patients



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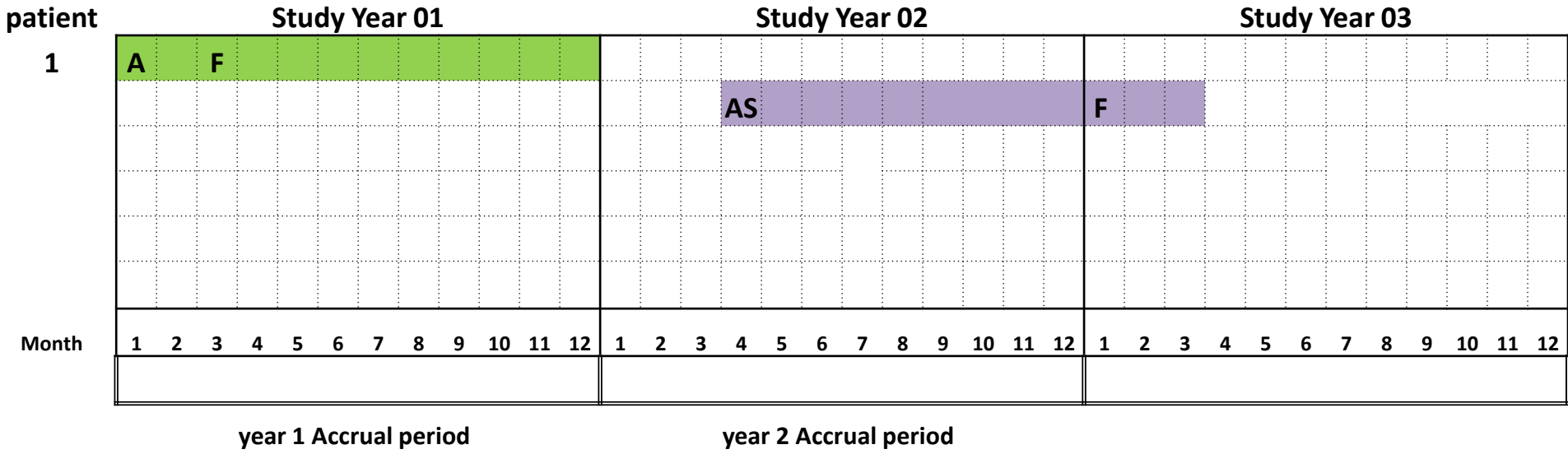

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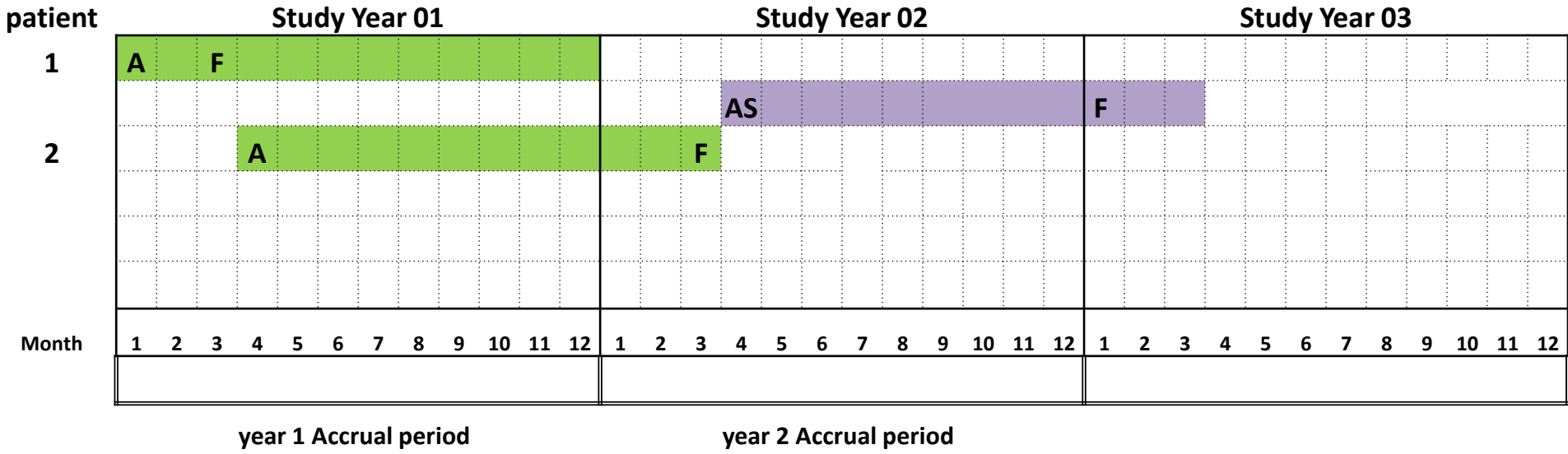

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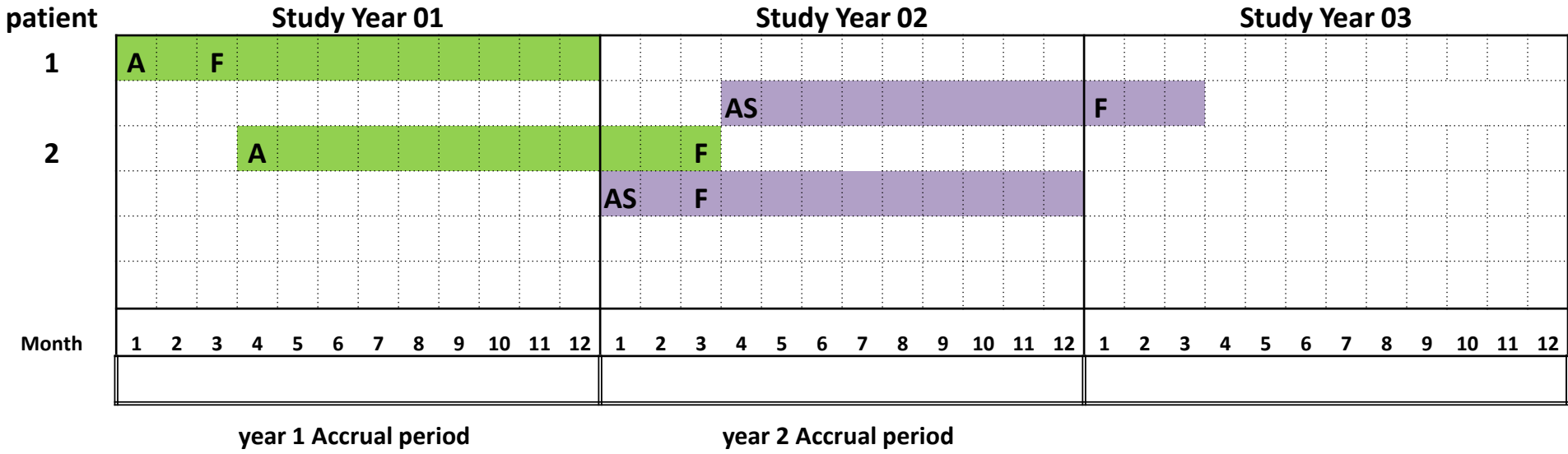

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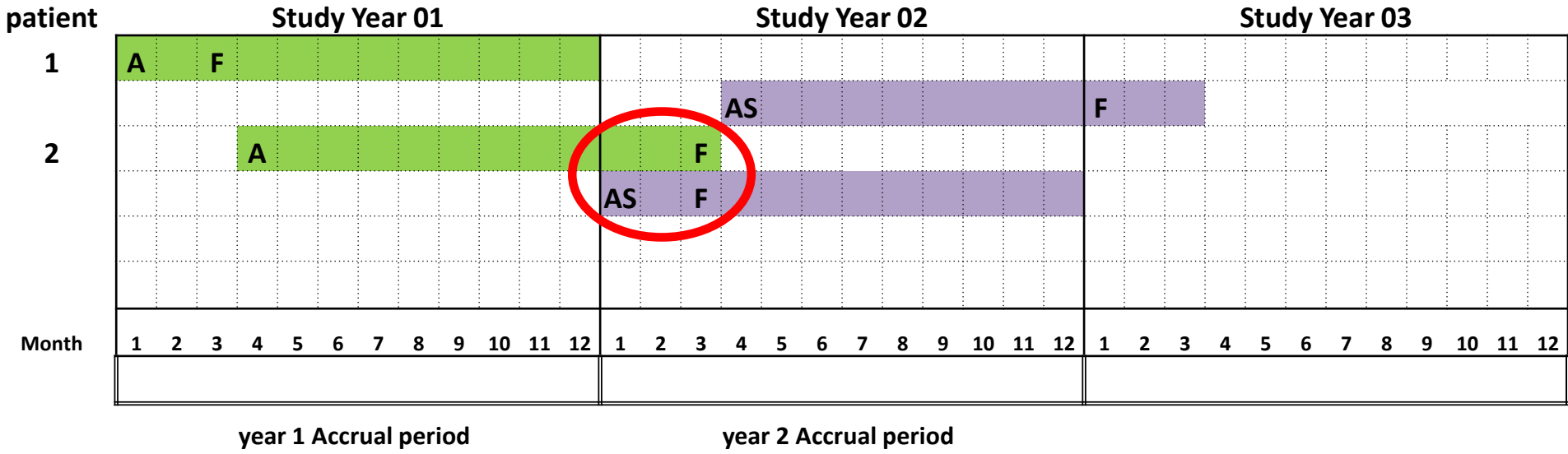

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Analytic Issue #2: Implementation Delays

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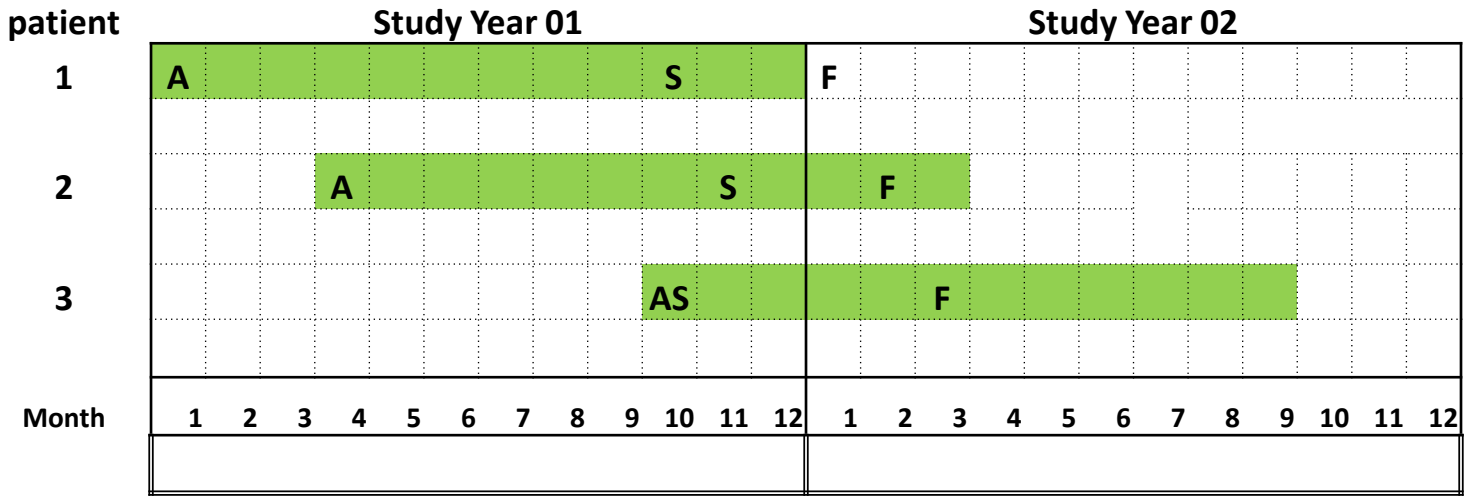
Illustration of Startup Lag

Intervention Clinic Patients



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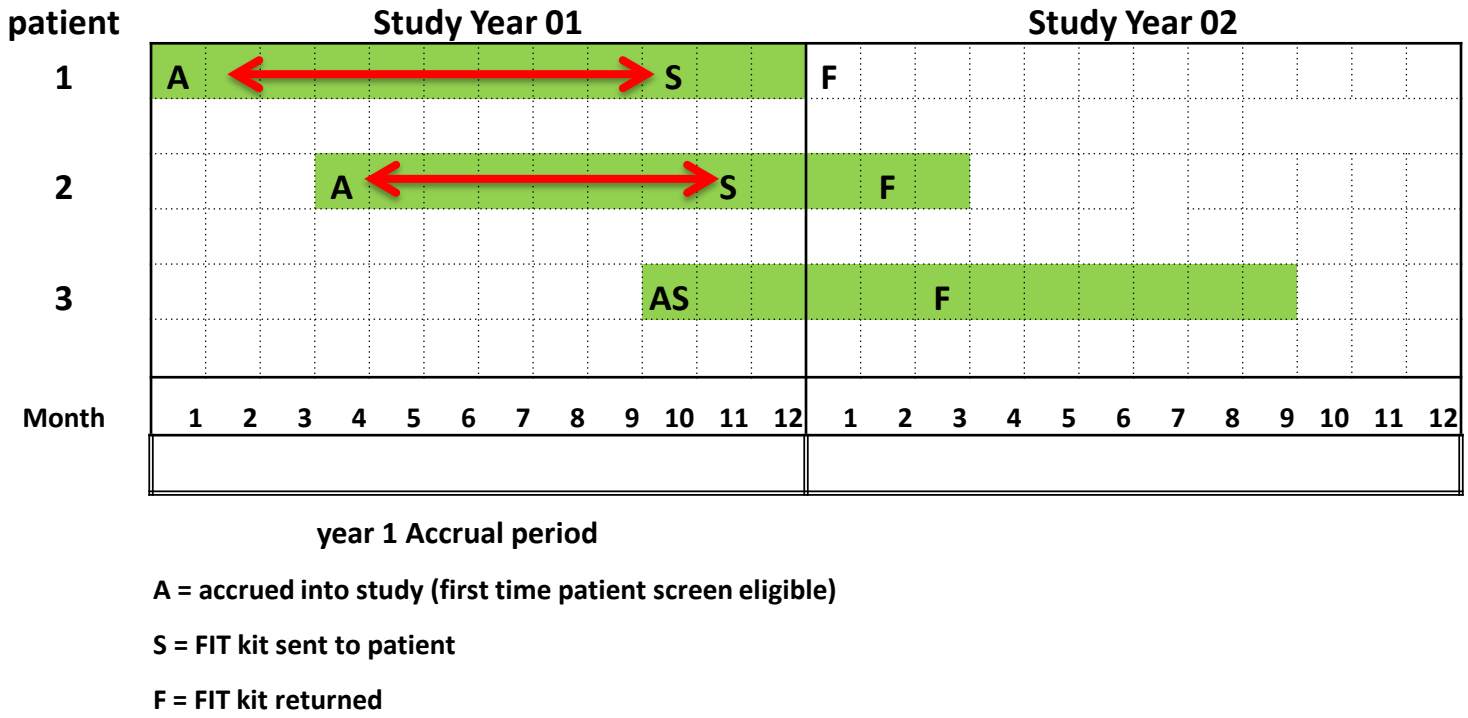

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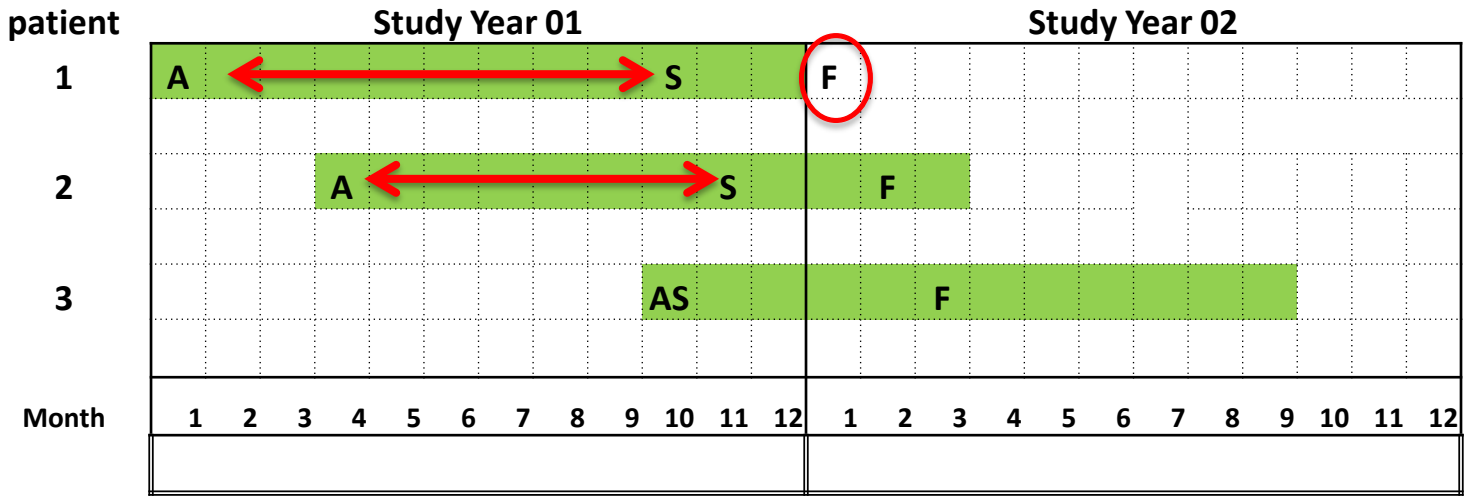

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- Influx of new patients generated by ACA and leadership turnover at some sites has led to delays in scheduling visits that cause some patients to no longer meet criteria for “active clinic patient” once rollout does begin
  - Reporting workbench only shows individuals who still meet the 12-month visit window requirement
  - Impact of this has been exacerbated by implementation delays

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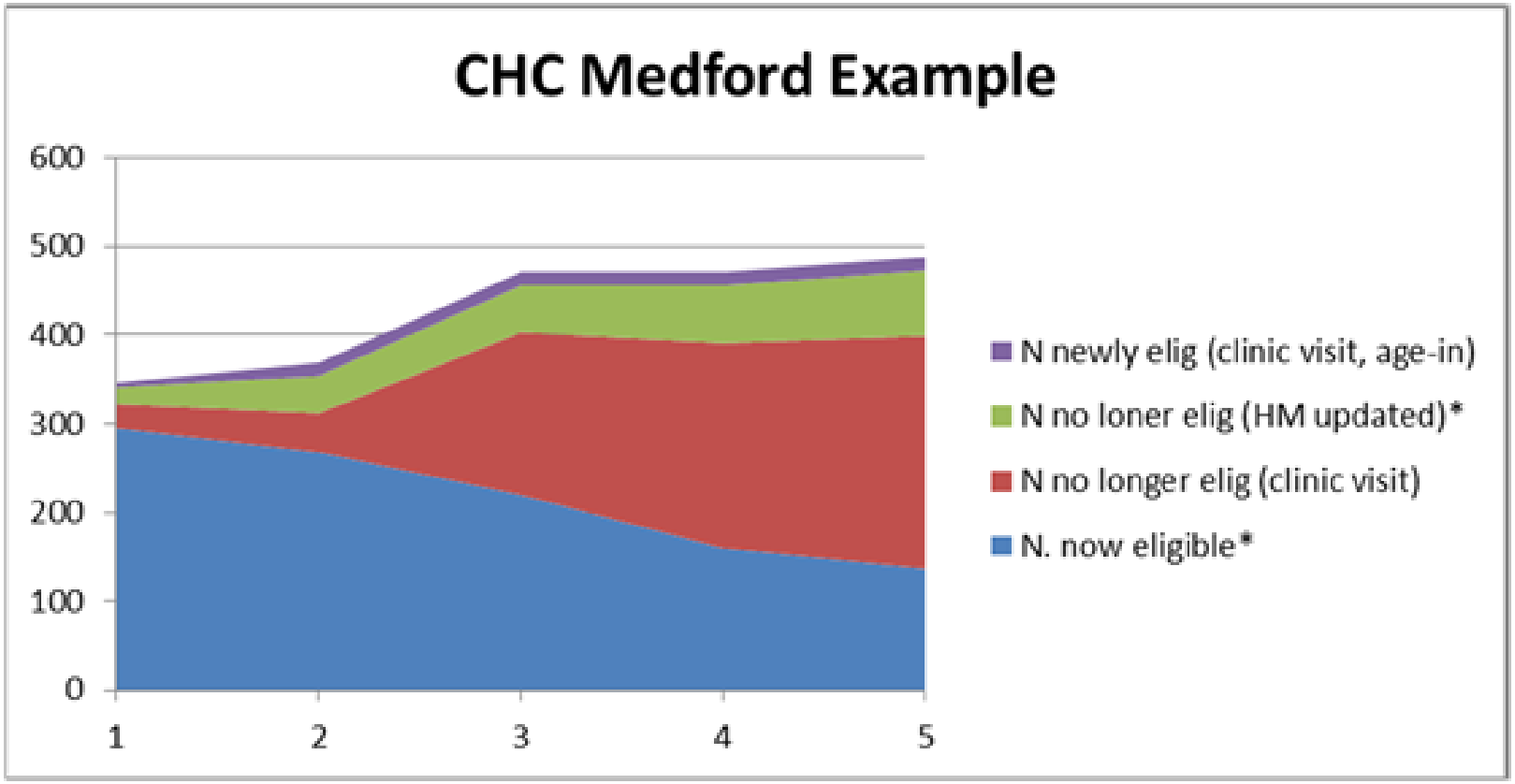
Illustration of Loss of Clinic Visit Eligibility



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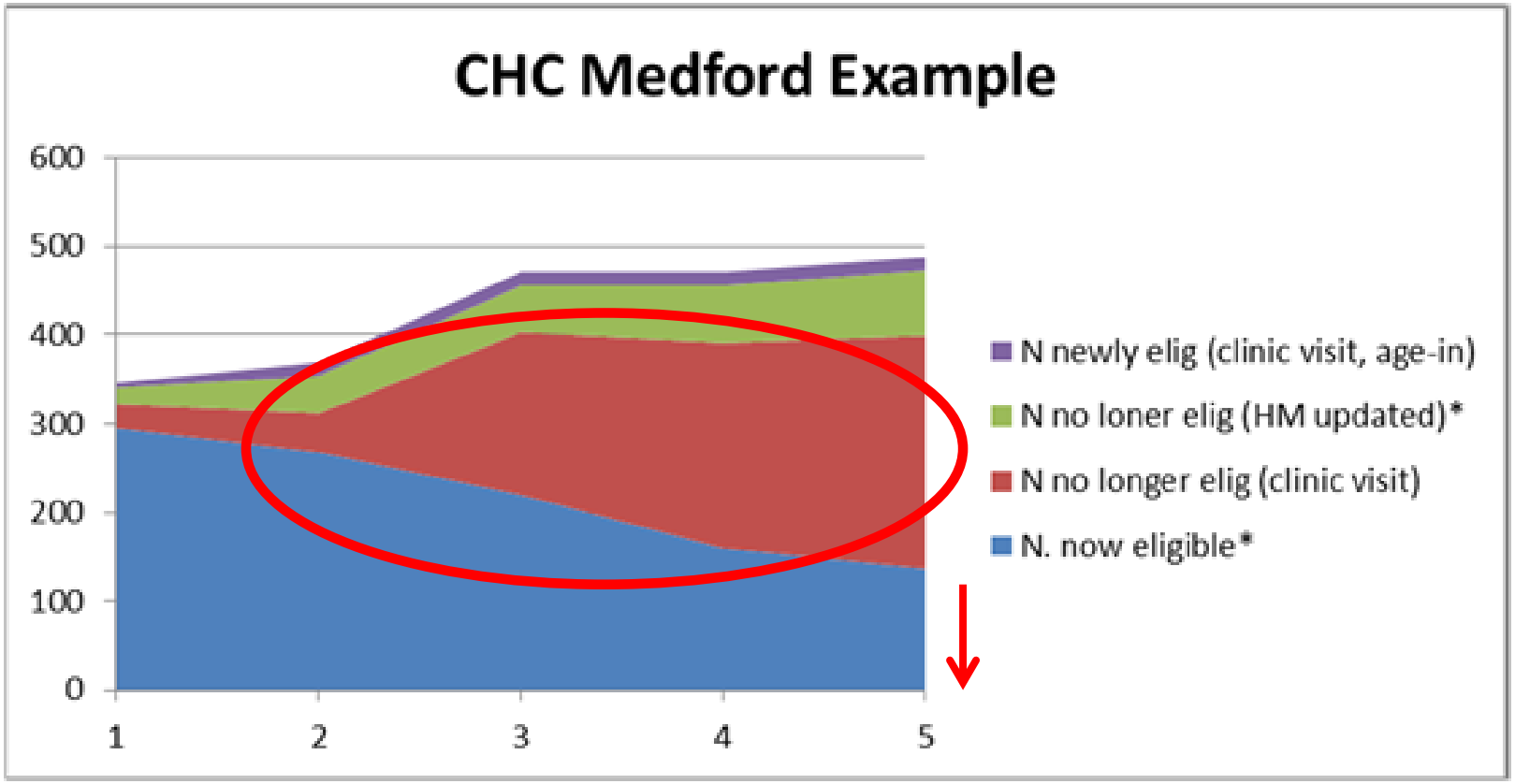

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Impact:

- Msmt window out of sync with “true” start of intervention
- Some participants never receive intervention, though still in analysis sample

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Analytic Issue #3: Longitudinal vs Cross-sectional Framework for Year 2

- Going through the exercise of laying out these scenarios highlighted one further issue.
  - Always planned to look at the year 2 data as part of secondary analyses
  - Some study questions are clearly longitudinal in nature
    e.g., how many intervention subjects complete a FIT in both years 1 & 2?
  - But the question of what does the year 2 rollout in control clinics look like is more of a cross-sectional question.

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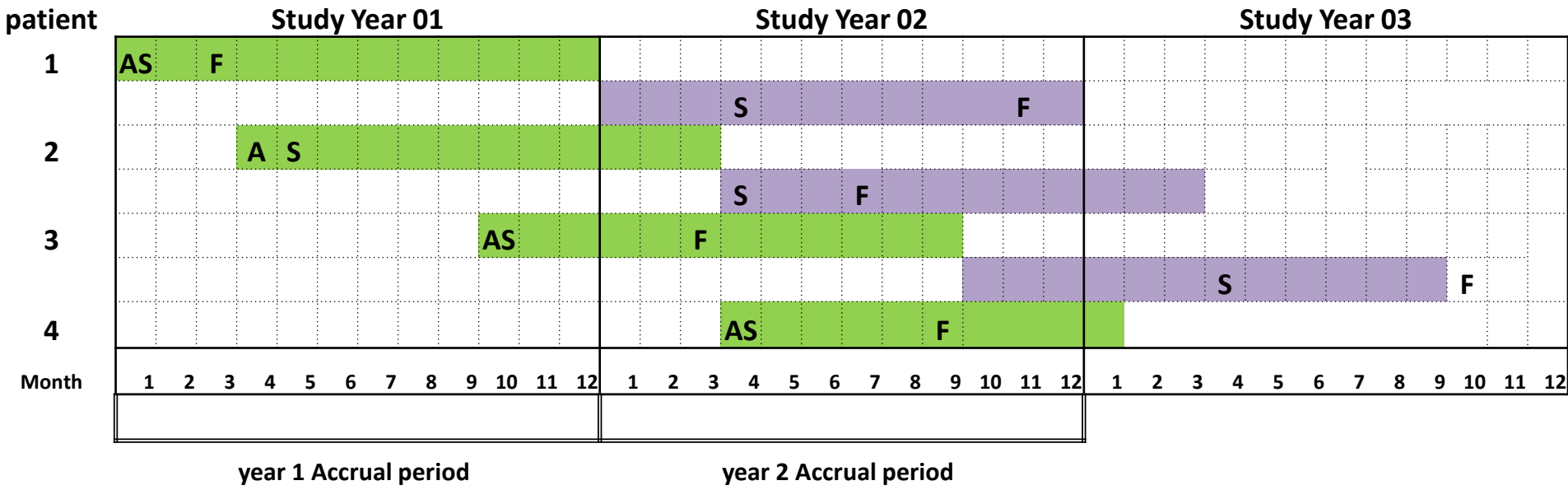
Impact:

- Raises ambiguity about how we should define our analysis sample for year 2.

Longitudinal vs Cross-sectional Perspective

Intervention clinics



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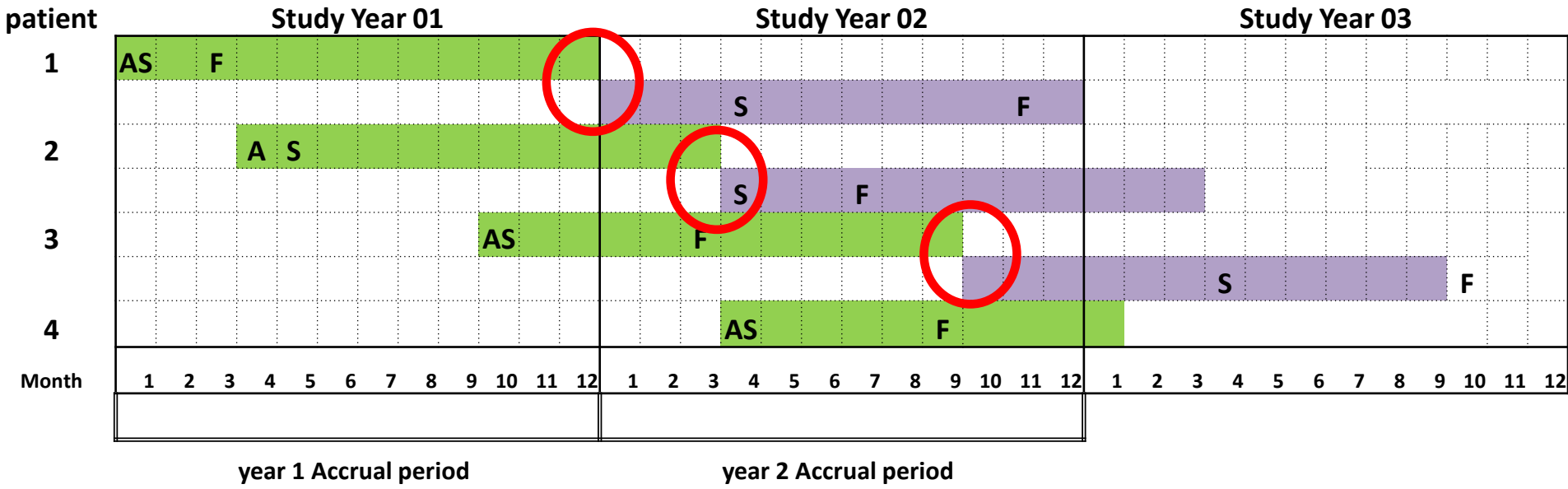

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Choice seem obvious:

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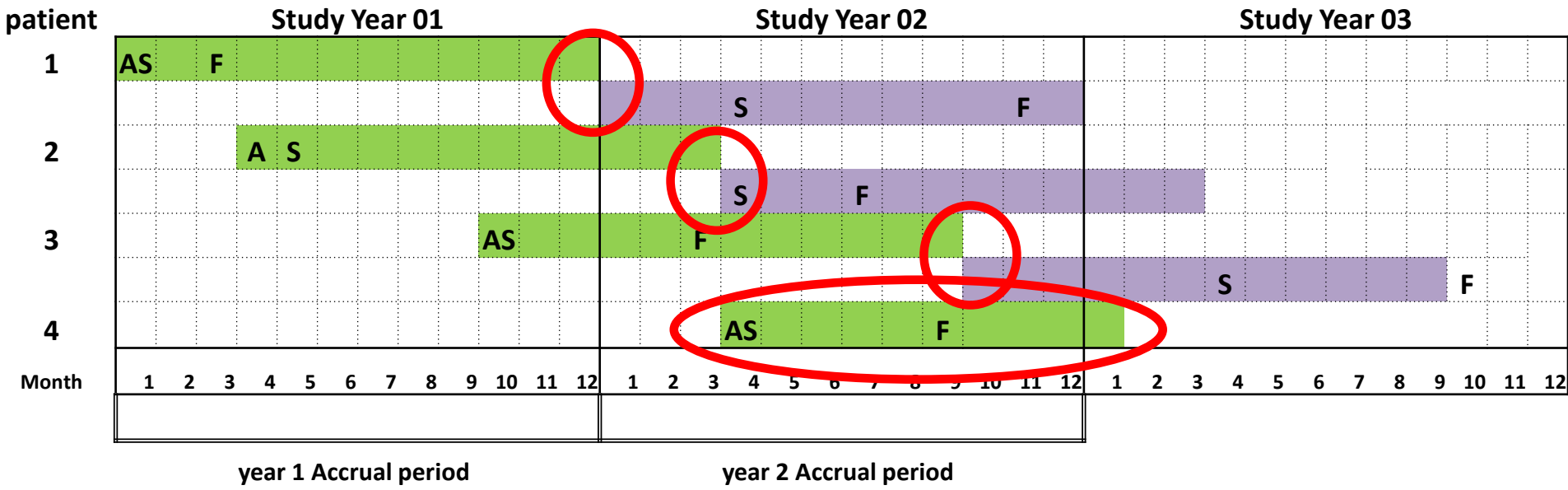

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Choice seem obvious:

- **year 2 abuts year 1 for already accrued pts**
- **continue to accrue new patients as they become eligible**

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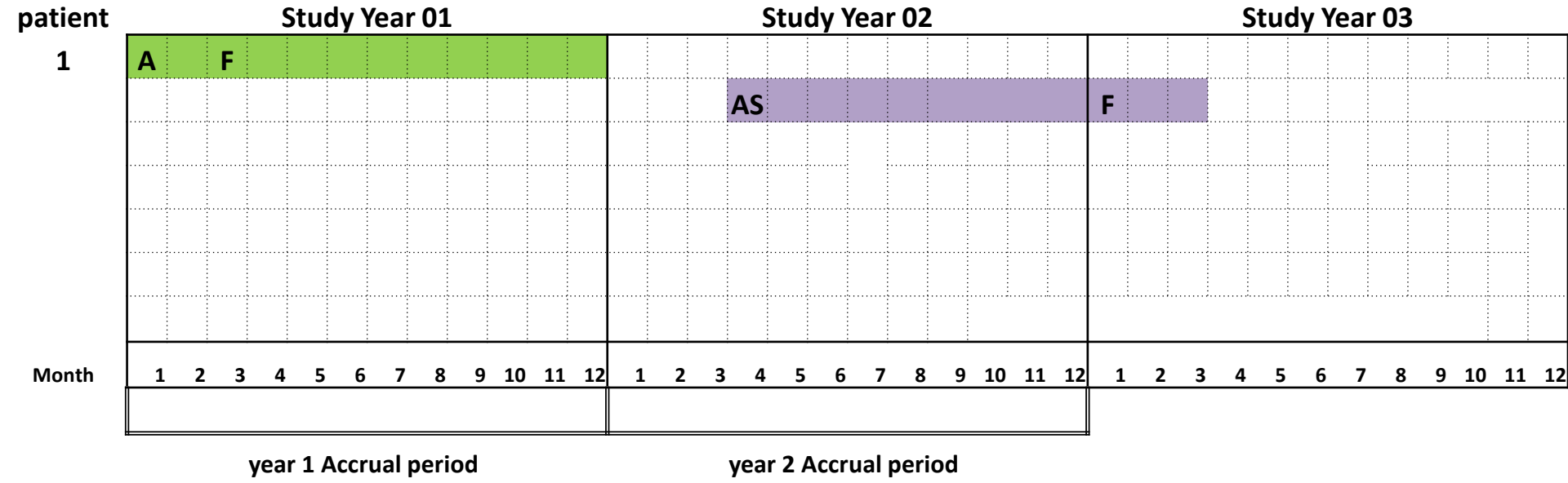
Longitudinal vs Cross-sectional Perspective

Control clinics



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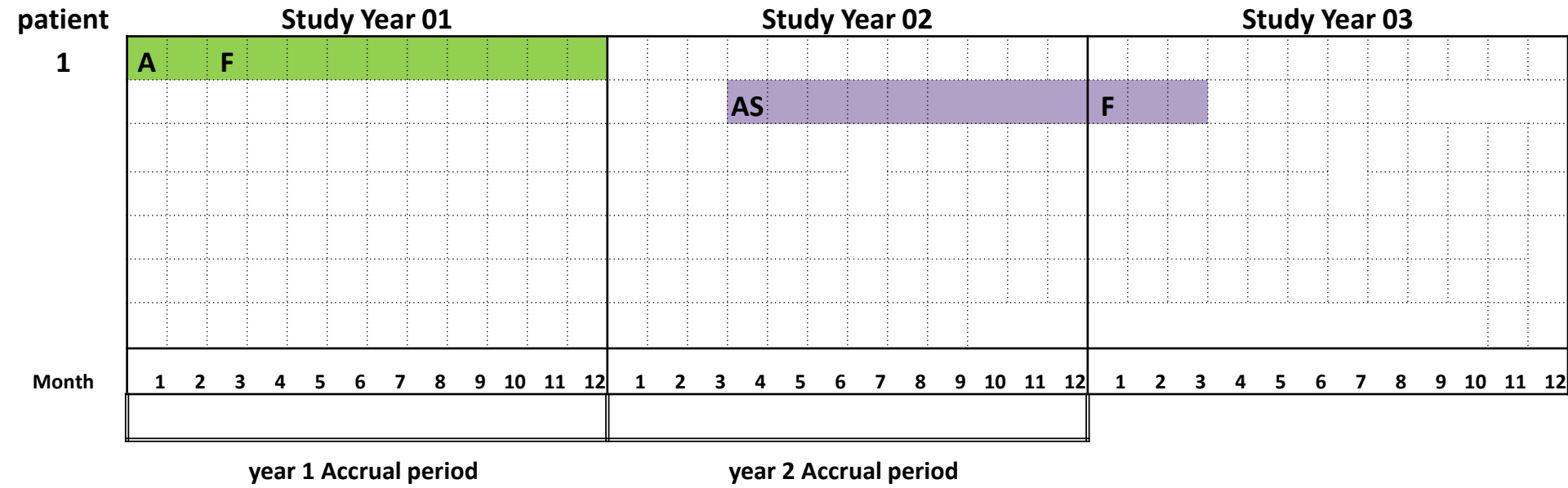

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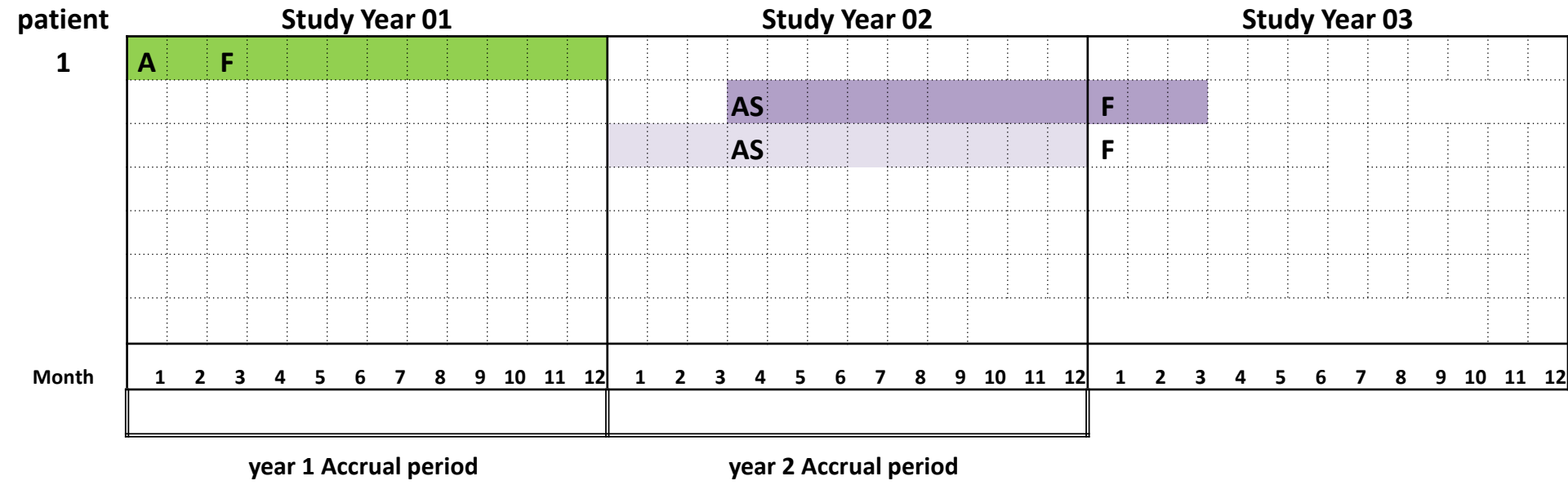

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Note that this is distinct from the overlap issue, which doesn't even come into play in this example.

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Longitudinal vs Cross-sectional Perspective

- If we want to ask what is lag from mailing of a FIT kit to its actual return, that implies yet a totally different way of measuring windows
  - Limit analysis to those who were ever mailed a FIT kit
  - Measure time from date FIT kit was mailed

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Recap

- Inability to selectively turn on intervention for control clinics in year 2 creates overlap of msmt windows

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- Delayed rollout in year 1, coupled with external factors and our use of real-time intervention tool, means current analysis plan will underestimate the true impact of the intervention

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- Inability to selectively turn on intervention for control clinics in year 2 creates overlap of msmt windows
- Delayed rollout in year 1, coupled with external factors and our use of real-time intervention tool, means current analysis plan will underestimate the true impact of the intervention
- Ambiguity over how to frame analysis of year 2 data

Proposed Solutions

- We have considered numerous alternative analyses, all of which have limitations

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- My proposal is to stick with originally planned primary analysis, but present a series of alternative analyses and acknowledge in Discussion strengths and weaknesses of each and argue there for what we feel is “best” analysis

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Proposed Solutions

- We have considered numerous alternative analyses, all of which have limitations
- My proposal is to stick with originally planned primary analysis, but present a series of alternative analyses and acknowledge in Discussion strengths and weaknesses of each and argue there for what we feel is “best” analysis
- Nonetheless, still have to deal with overlap issue even for primary analysis

Addressing Overlap

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- Redefine accrual window plus msmt window to be no greater than 18 months
  - Do in same way for intv and control clinics to avoid bias
  - Use of longer msmt window and shorter accrual window will still give us time to see an intervention effect even despite delayed startup in year 1

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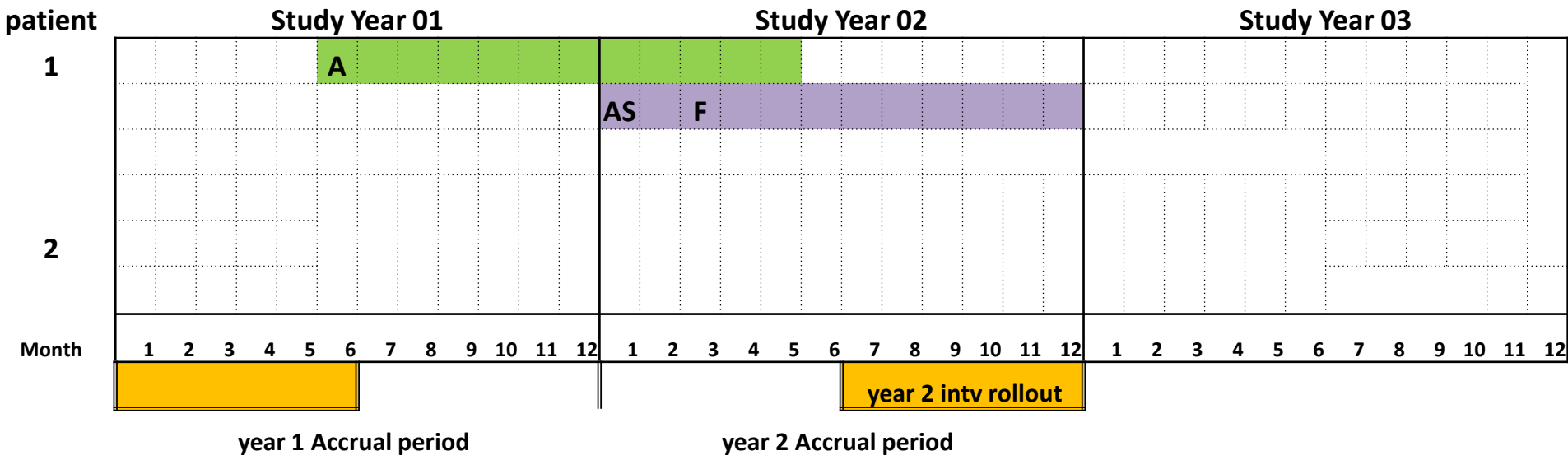
Dealing With Overlap:
Impact in Control Clinics

Control clinics



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6 month accrual period and 12 months msmt window

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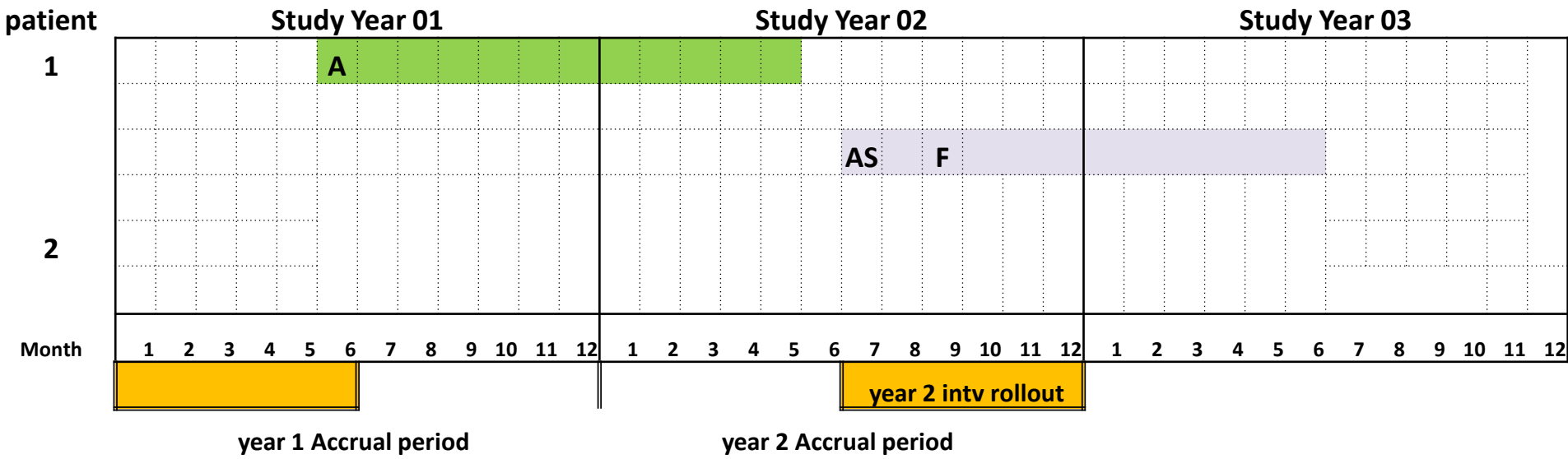

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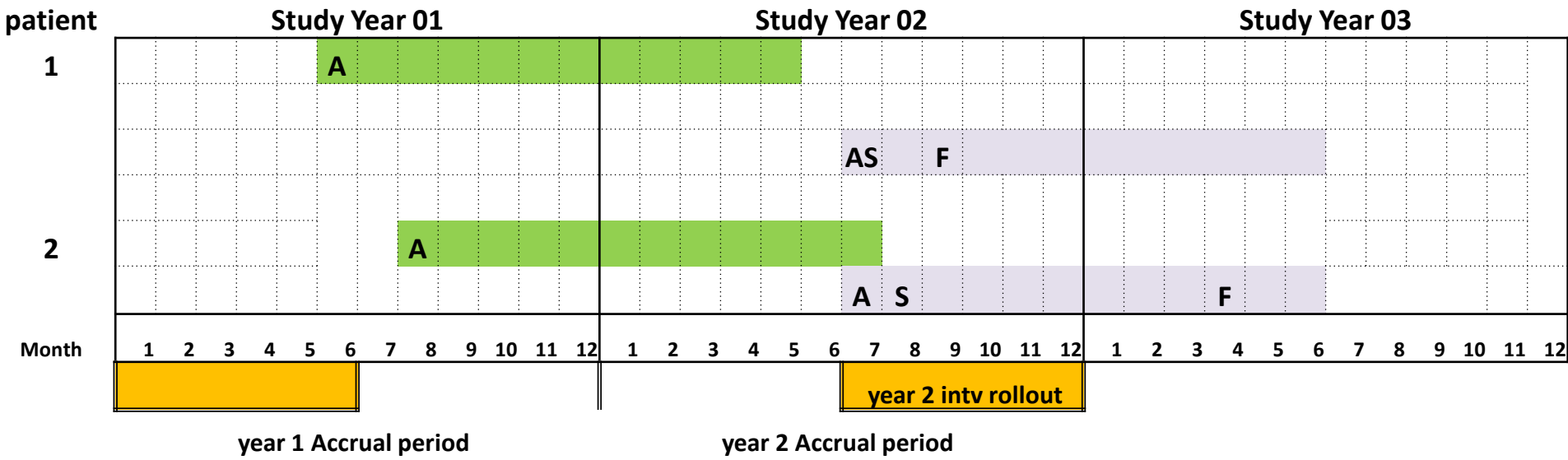

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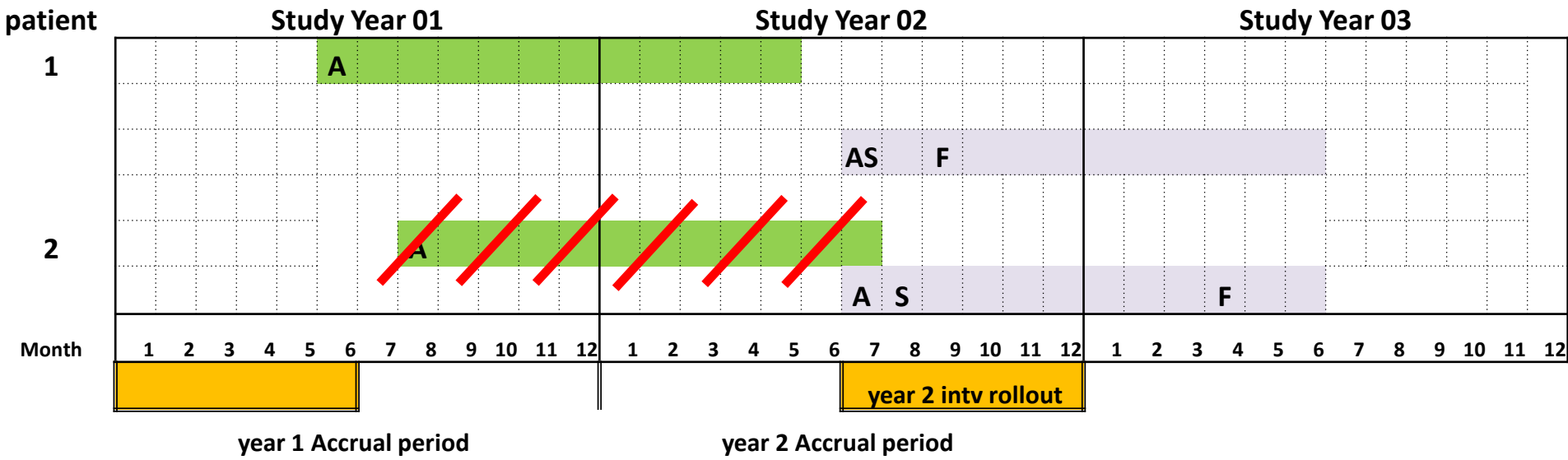

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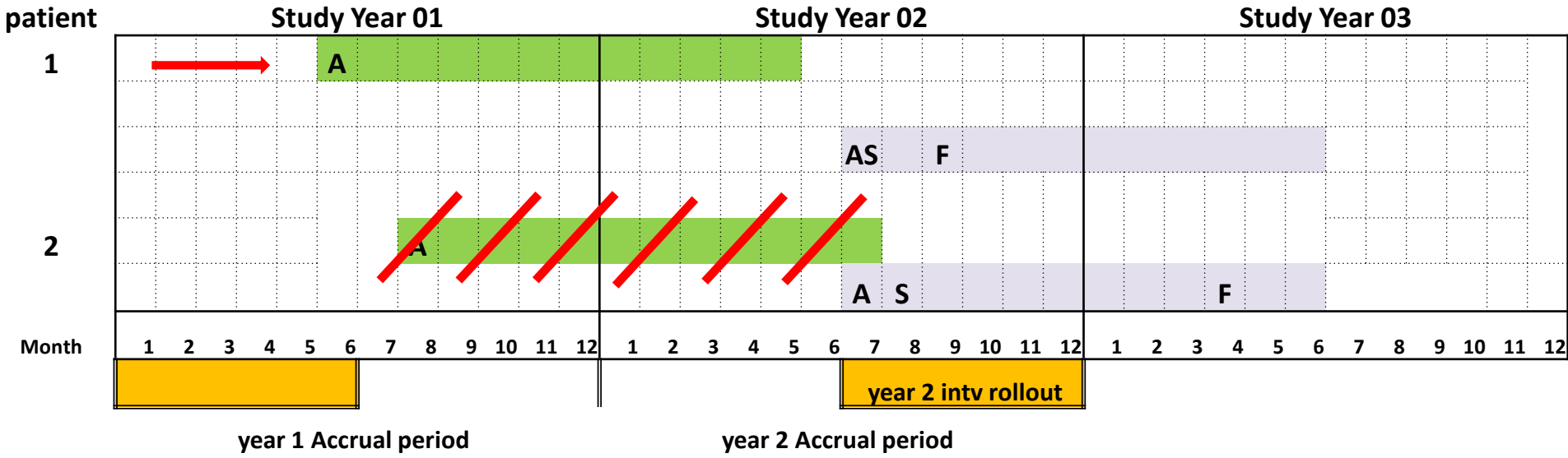

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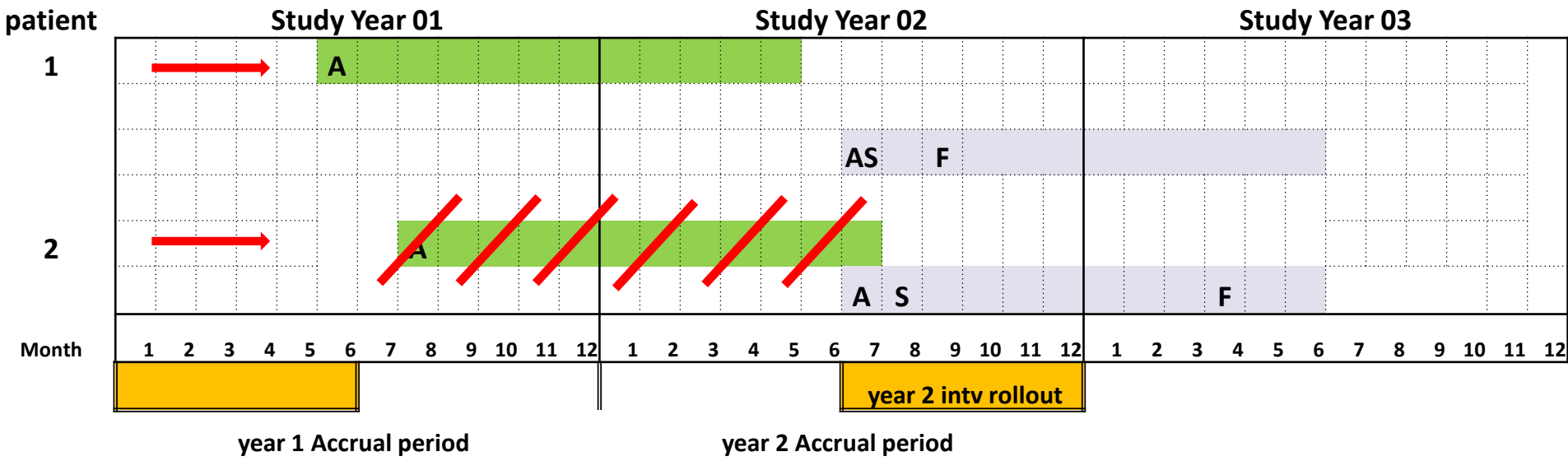

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- Patients accrued after month 6, for whom overlap would be an issue, are excluded from analysis sample

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Dealing With Overlap:
Impact in Intervention Clinics

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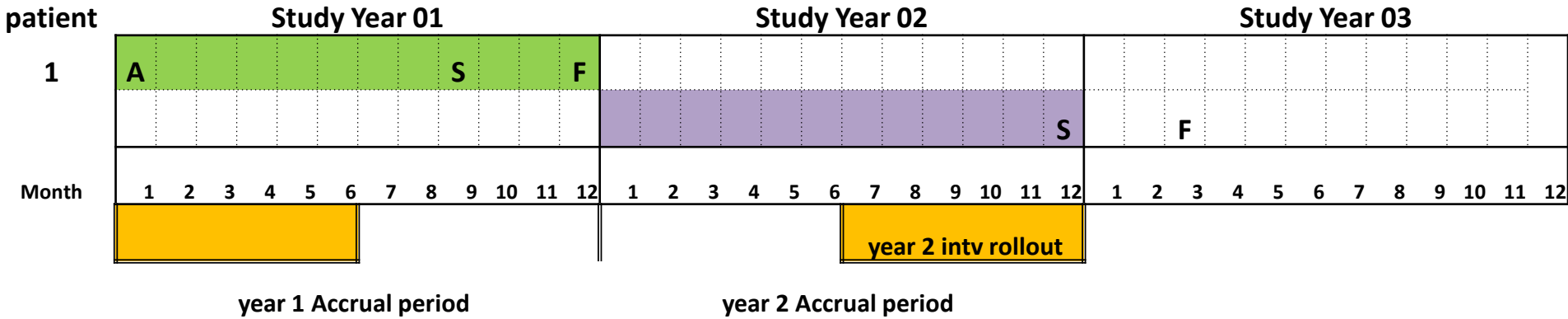

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Even with the delayed startup we still capture this intervention person's returned fit kit.

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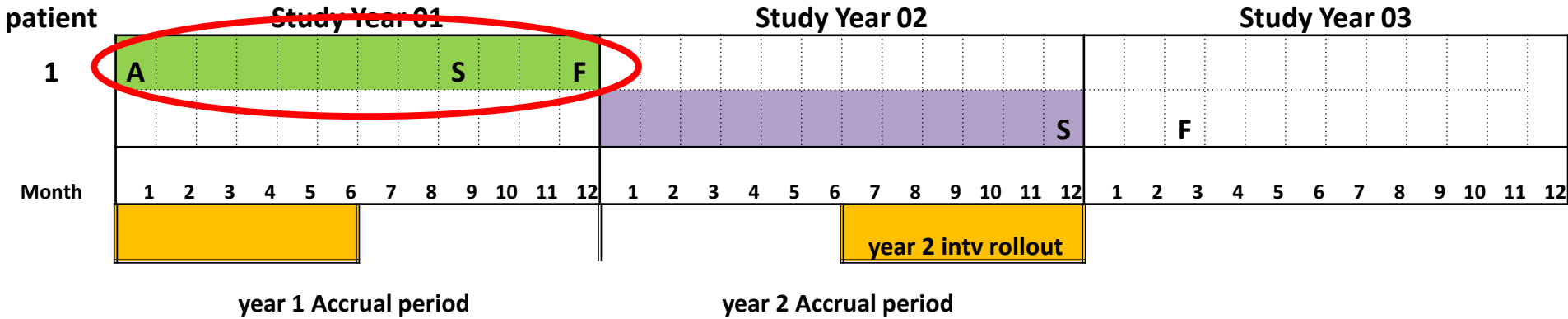
Impact in Intervention Clinics

Intervention clinics



A = accrued into study (first time patient deemed screen eligible)

S = FIT kit sent to patient

F = FIT kit returned

Even with the delayed startup we still capture this intervention person's returned fit kit.

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Addressing Overlap:
A further variant

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- Previous example assumed same accrual window (6 months) and msmt window (12 months) for everyone.

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A further variant

- Previous example assumed same accrual window (6 months) and msmt window (12 months) for everyone.
- Alternative is accrue through 12 months, but adjust msmt window to minimum of 12 months or time to start of intervention rollout in year 2

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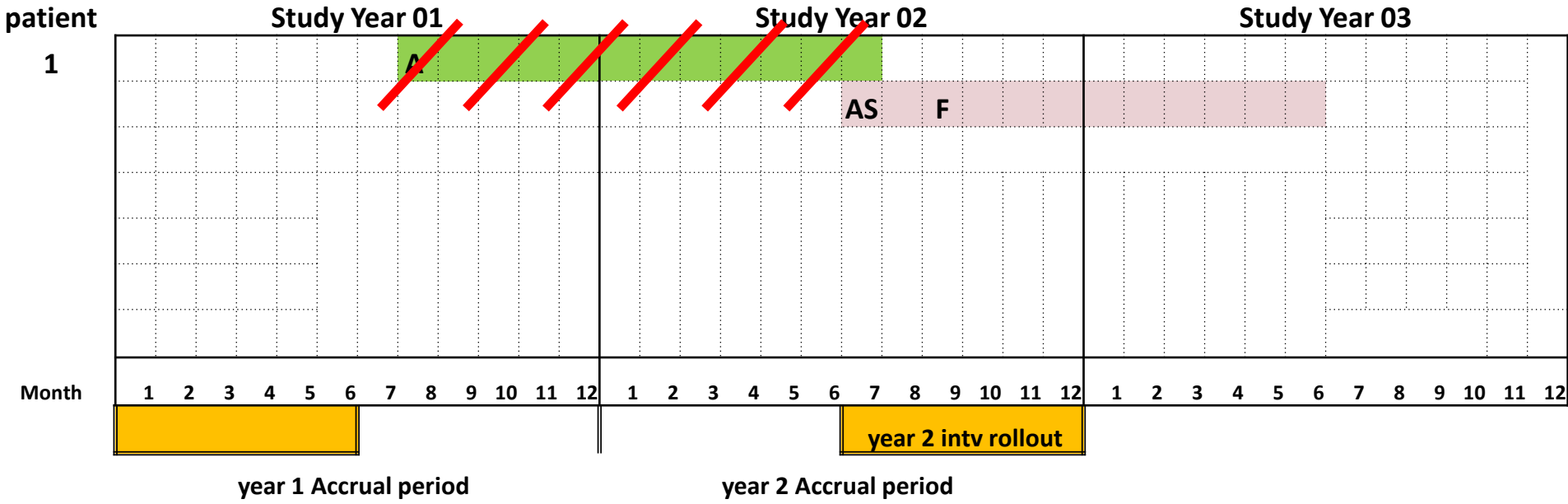
Addressing Overlap:
A further variant

Control clinics



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- Under earlier rule we dropped this person from year 1 analysis sample

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A further variant

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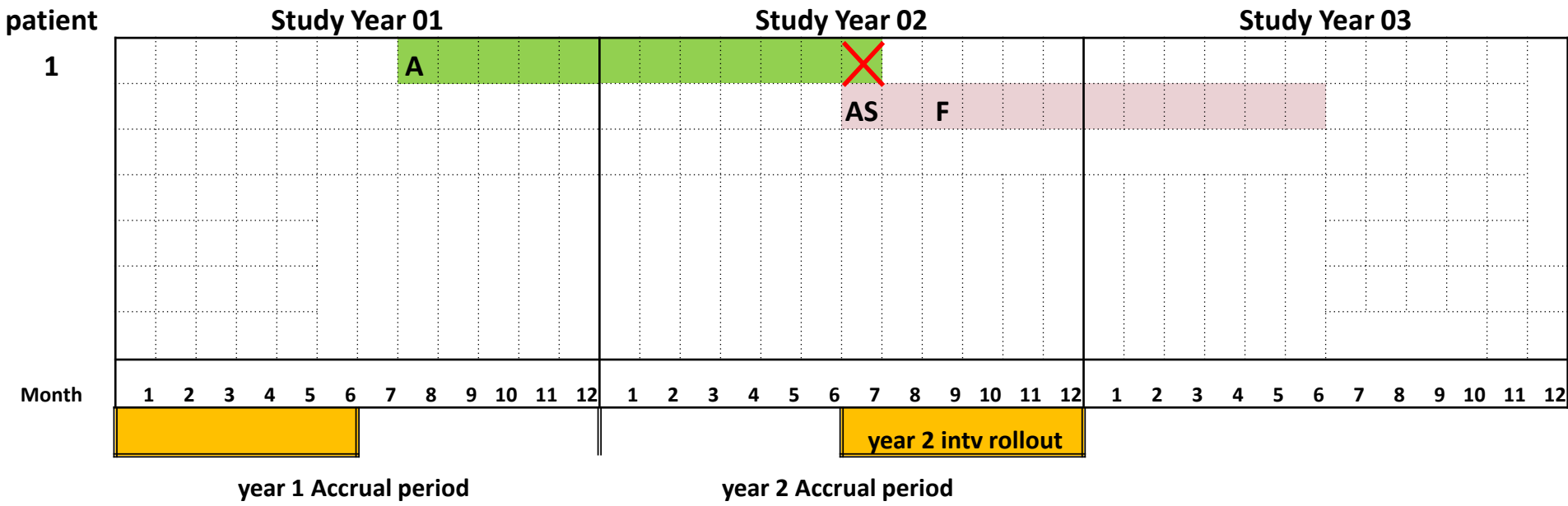

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- Now include, but with a shortened msmt window

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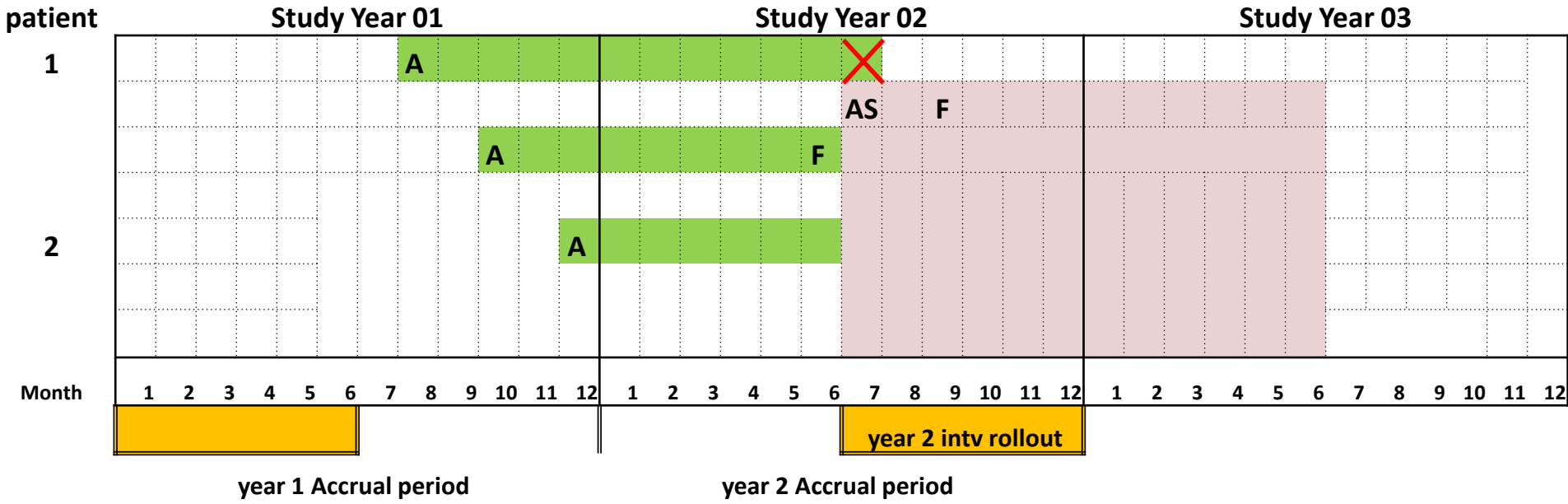

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- Those accrued even later have even shorter msmt windows

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A further variant

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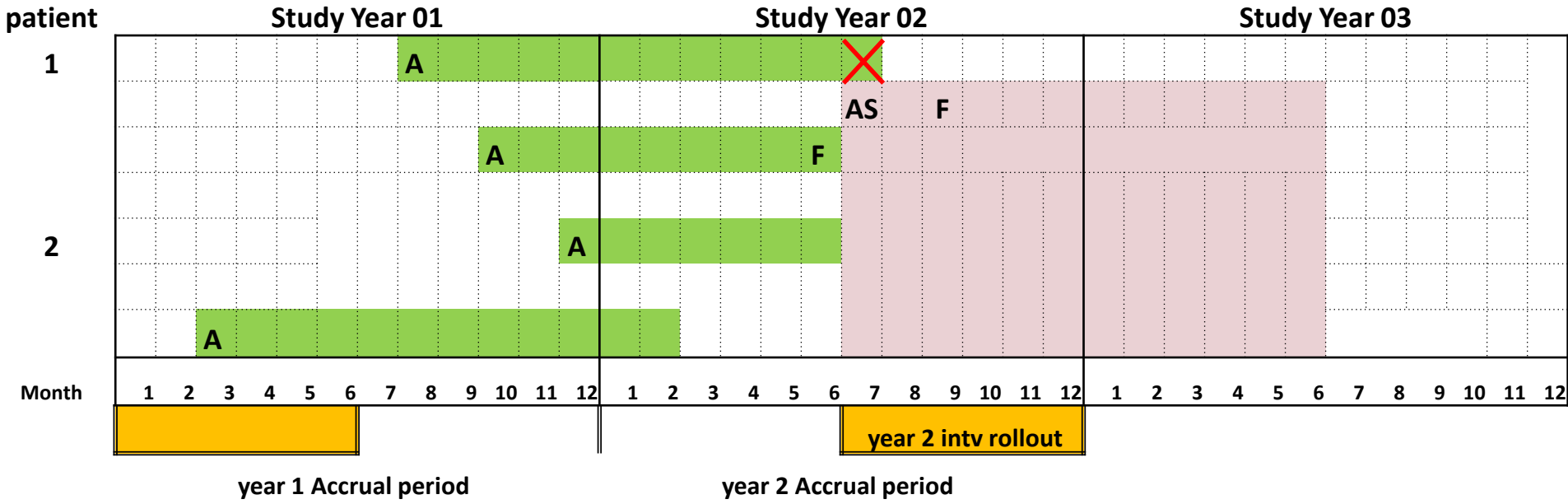

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- Early accruals still followed for no more than 12 months

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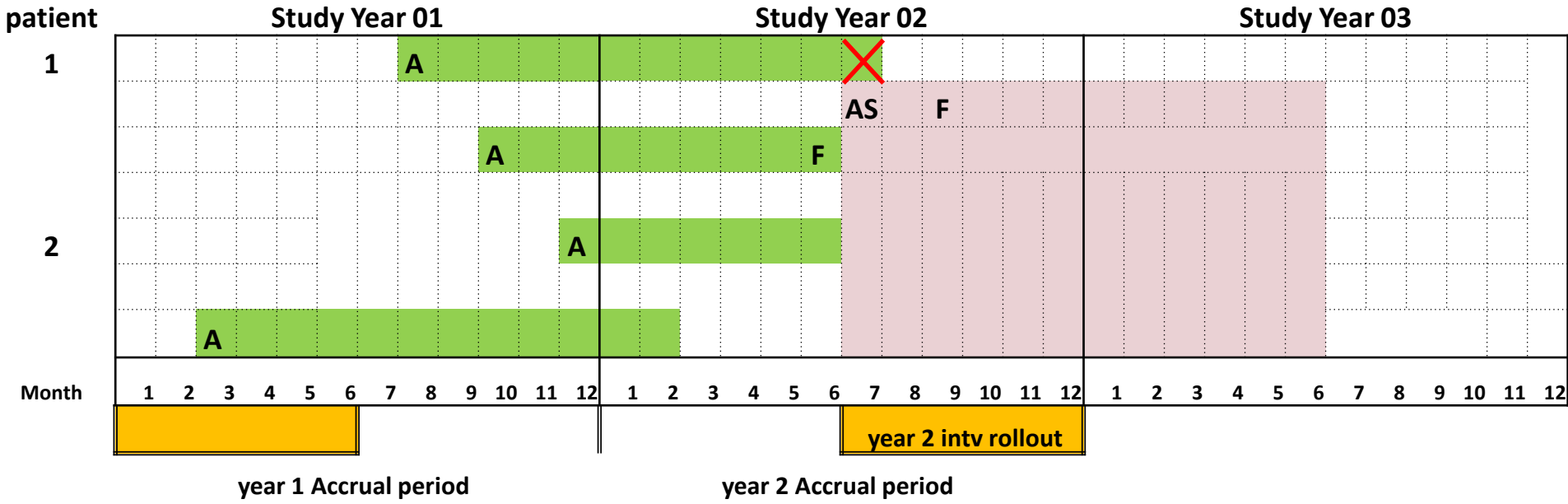

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Bottom Line:

- Accrue through full 12 months
- Msmt window varies, but ≤ 12 months
- No overlap with year 2 rollout

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Addressing Overlap:
A further variant

Pros:

- Doesn't waste any subjects
- Uses maximum available window while still avoiding overlap
- Can still be done in comparable manner for intv and control clinics
- Unlikely to introduce any systematic bias into analysis

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- Perhaps okay since lag makes meaning of a 12-month probability somewhat meaningless anyway
- We also know from previous work that most FIT kits will be returned within 3 months of mailing anyway

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Secondary Analysis 1

Ignore first 6 months of data and don't start accruing subjects until August 2014

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Only accrue for 6 months and either use 6-month fixed msmt window or varying windows from 6-12 months as described previously

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Secondary Analysis 2

Redefine eligibility criteria to require clinic visit in past 1 or 2 months rather than past 12 months

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Same overlap issues as for primary analysis plan

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- Probably won't use since
  - Likely won't buy us much compared to previous approach, which should largely address this problem too
  - Limited staff resources

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Secondary Analysis 3

Our analytic problems essentially arise because:

1) We are trying to estimate a steady state process during what is really a startup year
2) Our msmt and accrual windows are out of sync, which causes conceptual problems when we get to year 2

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Secondary Analysis 3

Our analytic problems essentially arise because:

1) We are trying to estimate a steady state process during what is really a startup year
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Might a fundamentally different approach overcome these issues?

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Step Wedge Design Framework

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- Use as our outcome a HEDIS-like measure that is assessed on a fixed calendar basis for everyone

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Step Wedge Design Framework

	Baseline	Year 1	Year 2
Group 1	Usual Care (UC)	UC	Startup
Group 2	UC	Startup	Steady State

One observation per clinic (“HEDIS” score), though in theory could calculate for subgroups similar to current analysis plan

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- No overlap issues to worry about
- Gets at a more policy relevant metric

Cons:

- Doesn't address direct impact of intervention
  - Denominator includes patients with existing coverage from prior colonoscopy or sigmoidoscopy and hence aren't candidates for intervention

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Step Wedge Design Framework

- What to do about delayed rollout in year 2?
  - Do we start “year 2” in month 19 and ignore months 13-18, or do we start in month 13?

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  - Year 1 startup effect includes all of the delay due to training, etc
  - That is still happening in months 13-18, we have just delayed turning on of the intervention report for the clinics
  - However for practical purposes clinics didn’t start using this report for at least six months anyway in year 1, so we are just formalizing in year 2 what happened anyway in year 1.

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Framing year 2 analyses

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- Different questions may require us to build totally different data files that not only include different subsets of the total sample, but that also have fundamentally different data structures.

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Framing year 2 analyses

- Key realization is that we aren't comparing intervention versus control clinics in year 2 so much as we are asking a series of implementation questions
- Different questions may require us to build totally different data files that not only include different subsets of the total sample, but that also have fundamentally different data structures.
- Emphasizes the need to be very explicit about the questions we want to ask and what sort of data files will be required to answer them

Summary

- The challenge of implementing pragmatic trials that are embedded within large, complex health systems are likely to lead to a variety of issues that may threaten the validity (or at least utility) of the primary analysis plan

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Summary

- The challenge of implementing pragmatic trials that are embedded within large, complex health systems are likely to lead to a variety of issues that may threaten the validity (or at least utility) of the primary analysis plan
- A number of alternative, secondary analyses may need to be considered to facilitate a more robust interpretation of the intervention impact
- The specifics of our problems may not generalize to other studies, though I suspect they may more broadly typify the types of issues others will face

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Summary

Welcome comments on

- Our proposed solutions
- Whether you agree with me that the conduct of pragmatic trials is more likely to raise such issues
- How we might better design trials to minimize the impact of such issues

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