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Population Health Impact Model

Tobacco Merchants Association 2015 Annual Meeting

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Health Impact Assessment

What is Health Impact Assessment?

- **Health Impact Assessment**: procedures, methods, and tools used to judge the potential effects on the health of a population, and the distribution of those effects within the population
- **Objective**: apply knowledge and evidence about health impacts, in a social/behavioral context, to develop evidence-based recommendations that inform decision-makers → to protect/improve the population health

Decision-making and recommendations	Determining the magnitude, nature, extent and likelihood of potential health impacts, using a variety of different methods and types of information
Identification and assessment of impacts	Making explicit the trade-offs to be made in decision-making and formulating evidence-informed recommendations
Monitoring and Follow-up	Process of impact evaluation, monitoring and management of health impacts

(ECHP 1999)

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Modeling Health Impact of Reduced-Risk Products*

- The lack of epidemiological data prior to marketing a product → inherent difficulties assessing the effect of introducing that product
  - Tobacco use behaviors (including initiation, switching, and cessation)
  - Health risks associated with the long-term use of the product

- Computational models of the health impact are tools that can inform it decision-makers by forecasting the health effects associated with different types of product use
  - **Pre-Market** → predictions of the potential impact related to marketing an RRP
  - **Post-Market** → refinement of the assumptions and tracking and evaluation of the actual impact related to marketing the RRP

- Based on existing literature Philip Morris International is developing a **Population Health Impact Model (PHIM)** to quantify the effect that marketing an RRP may have on the health of a population

*Note: Reduced-Risk Products (RRPs) is a term we use to refer to products that have the potential to reduce the individual risk and population harm in comparison to smoking combustible cigarettes

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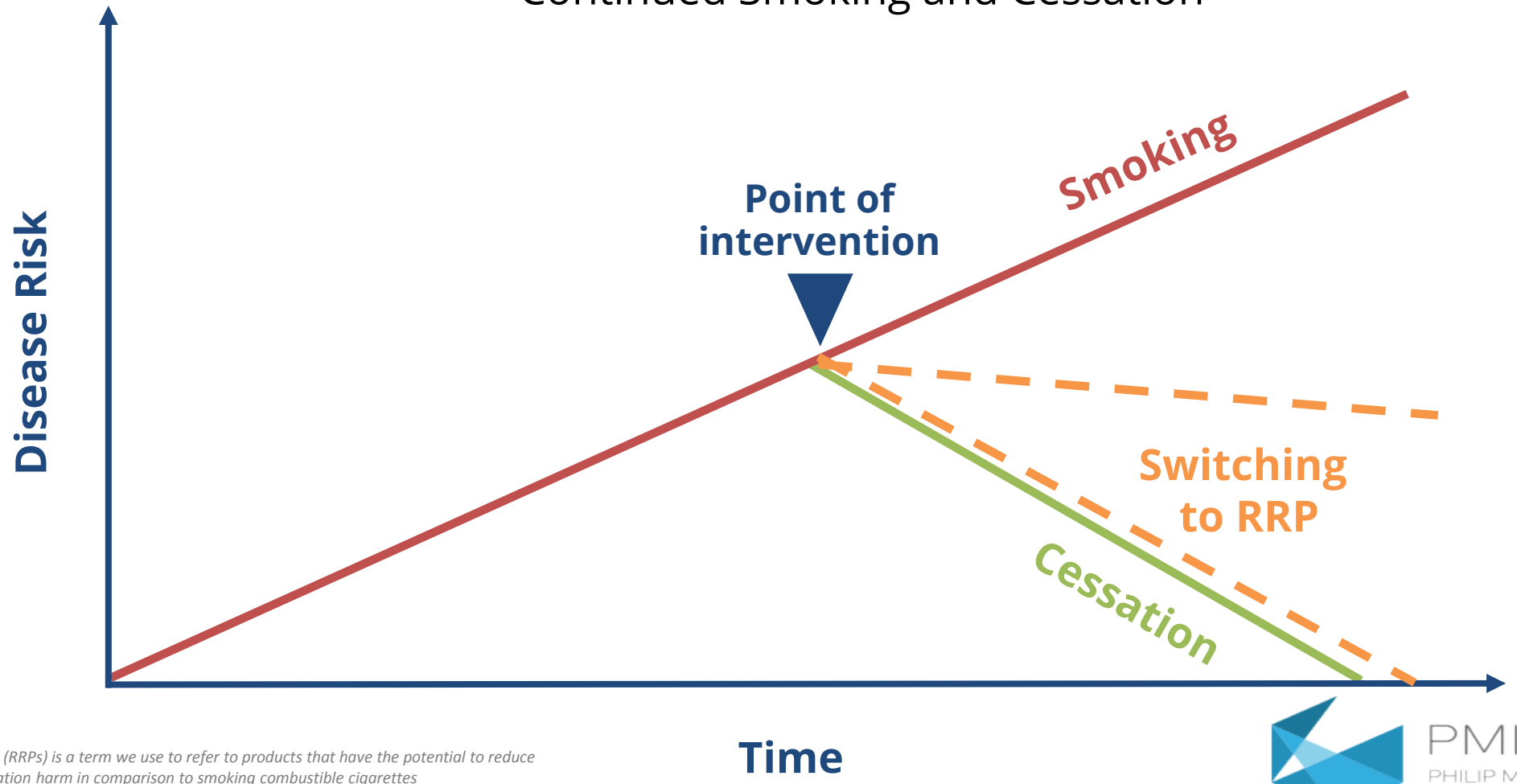
Assessment of Tobacco Risk Reduction

For tobacco health impact assessment the extremes are well established
Continued Smoking and Cessation



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The Model

PMI's Approach to Population Health Impact Modeling

PMI Approach to Modeling

- Rely on scientifically accepted epidemiological methods and data
  - Data and data sources are scientifically reviewed, published and publically available
  - Standard and well accepted epidemiological methodologies
- Goal = minimize the number of assumptions required by the model
  - **Tobacco Transition Probabilities** - set of assumptions for the distribution of and change over time in the smoking behaviors before and after the RRP introduction
  - **The RRP Factor ("F")** - a product- and disease-specific set of assumptions quantifying the health risks associated with RRP relative to smoking and cessation
- Ensure that the process for gathering, evaluating and modeling the data is explicit, transparent and balanced
  - Make the model publically available
  - Publish the modeling in peer reviewed journals
  - Thorough testing and validation of the model
  - Model is programmed using standard statistical software (SAS)

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Modeling Concept

A novel approach to assess the population health impact of introducing a Modified Risk Tobacco Product

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ABSTRACT

Based on the Food and Drug Administration's Modified Risk Tobacco Product (MRTP) Application draft guideline, Philip Morris International (PMI) has developed a Population Health Impact Model to estimate the reduction in the number of deaths over a period following the introduction of an MRTP. Such a model is necessary to assess the effect that its introduction would have on population health, given the lack of epidemiological data available prior to marketing authorization on any risks from MRTPs. The model is based on publicly available data on smoking prevalence and on the relationships between smoking-related disease-specific mortality and various aspects of the smoking of conventional cigarettes (CCs), together with an estimate of exposure from the MRTP relative to that from CCs, and allows the exploration of possible scenarios regarding the effect of MRTP introduction on the prevalence of CC and MRTP use, individually and in combination. By comparing mortality attributable in a scenario where the MRTP is introduced with one where it is not, the model can estimate the mortality attributable to CCs and the MRTP, as well as the reduction in the deaths attributable to the introduction of the MRTP.

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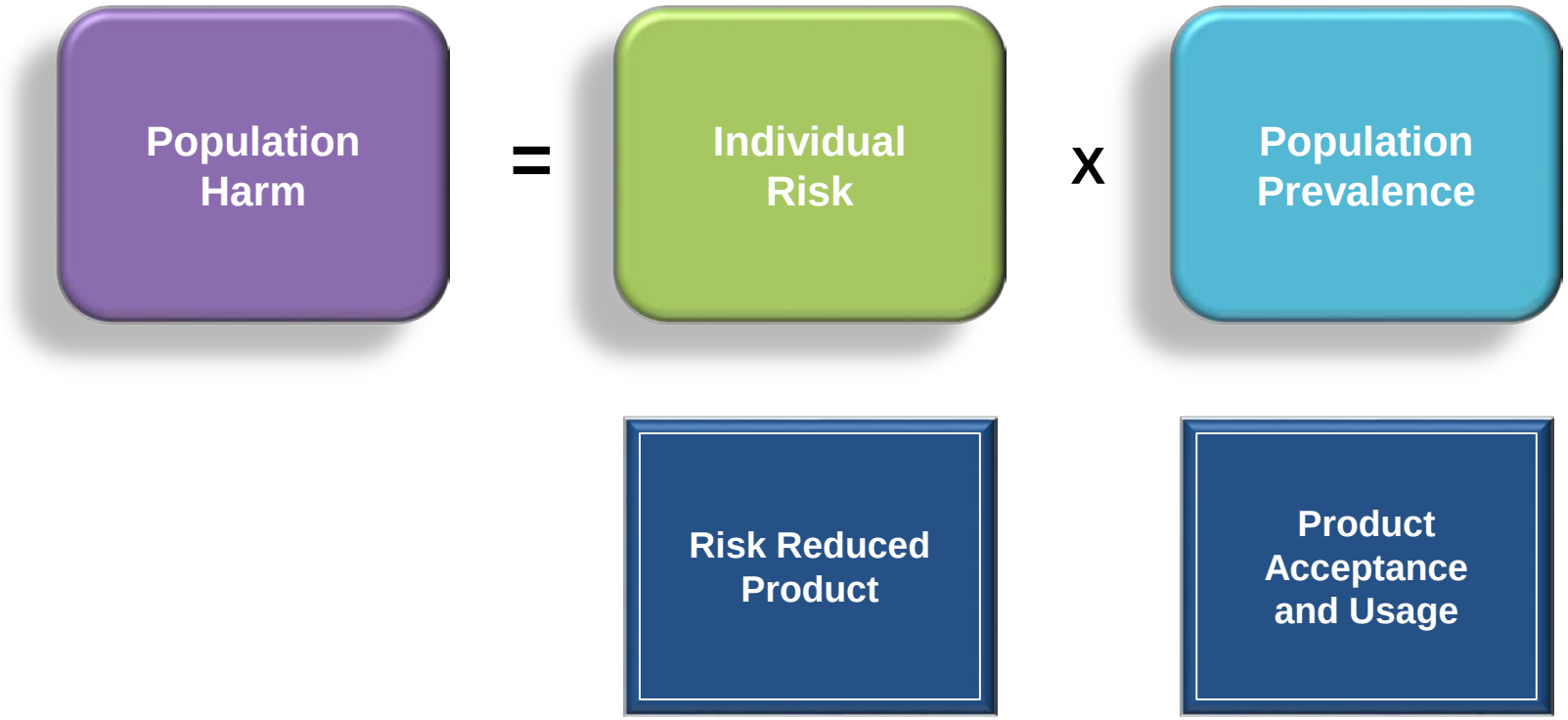
Defining “Population Harm”



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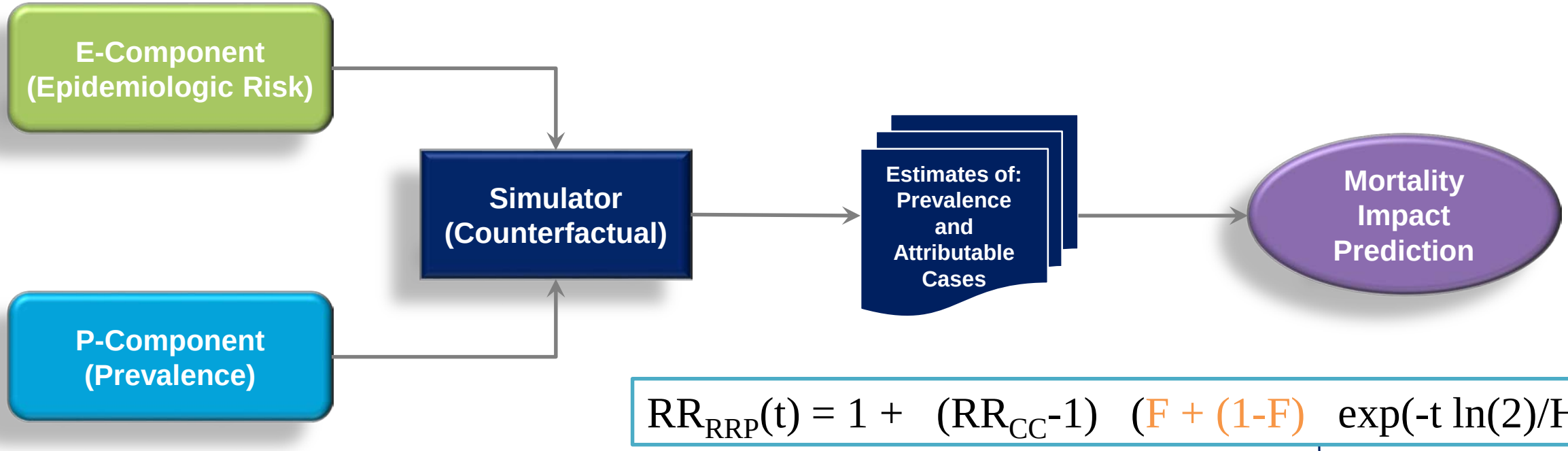
Population Health Impact Model - The Model



$$RR_{RRP}(t) = 1 + (RR_{CC}-1)\ (F + (1-F)\ \exp(-t \ln(2)/H))$$

Reduction of Risk Over Time – since Cessation

Fixed Data Required for the Model

- Population (country-specific)
- Disease mortality risks → Relative risk of smoking
- Disease mortality risks (reductions over time) → Cessation
- Tobacco use prevalences (age and sex – specific)

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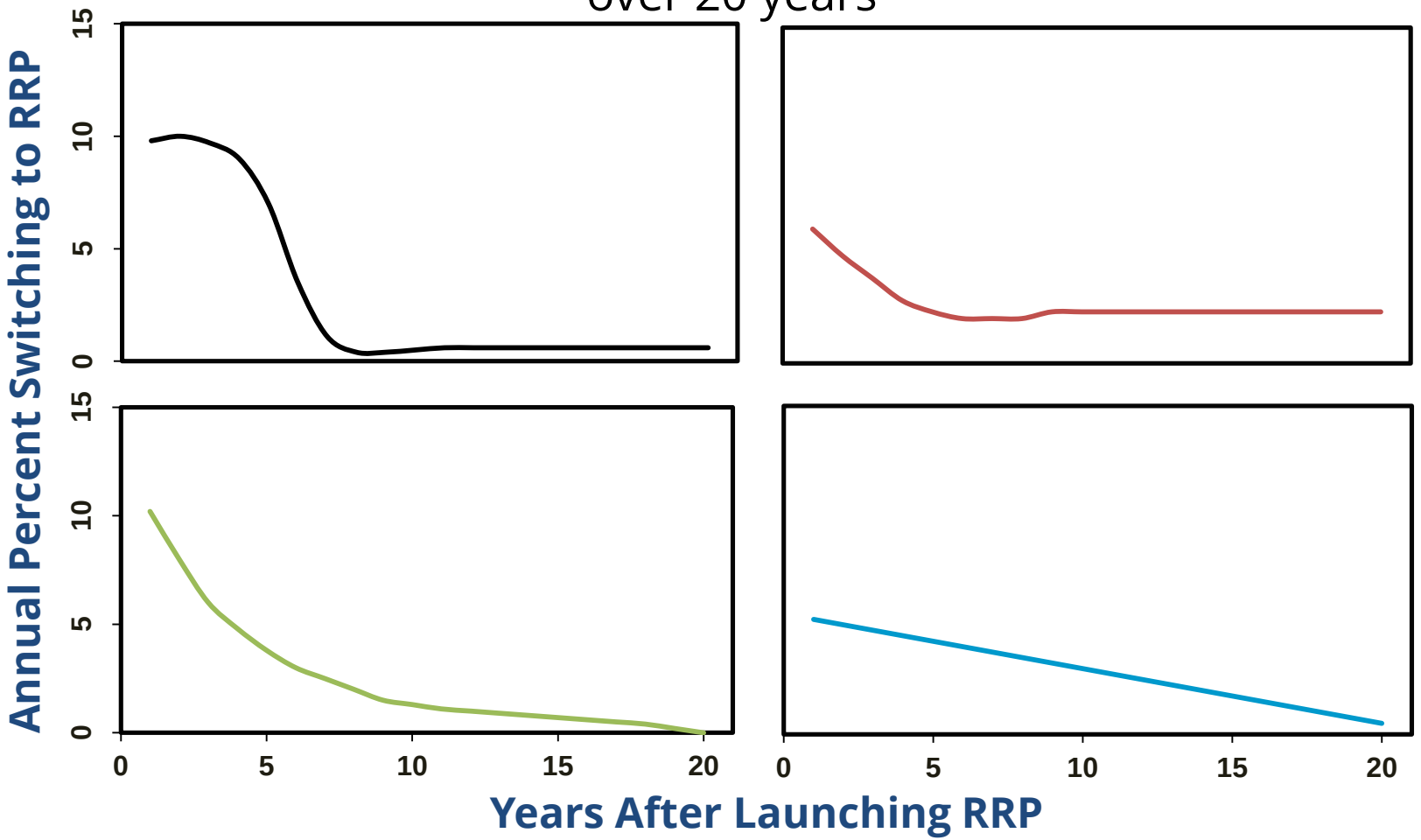
Tobacco Transition Patterns

P-Component

Each pattern correspond to a cumulative switching rate of 50% over 20 years



- Markov chain state-transition model
- Creates a hypothetical population for:
  - Null Scenario (without RRP)
  - RRP Scenario (with RRP)
- Tobacco transitions are unknown pre-market
- Initial estimates from:
  - Clinical and Actual Use studies
  - Intention to Use data

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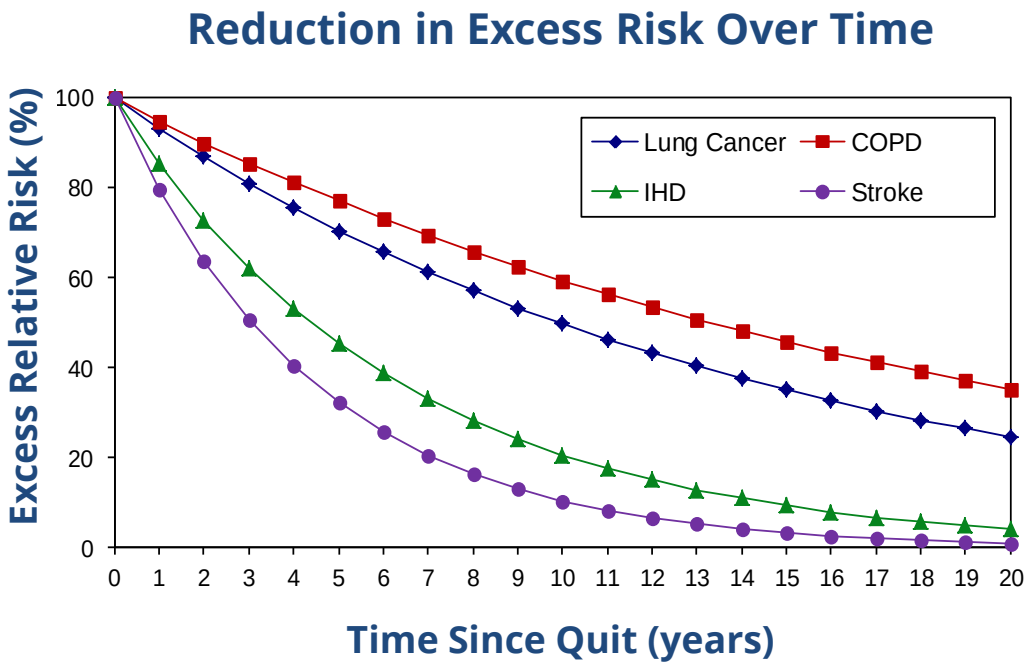
Negative Exponential Model

E-Component

- Relative Risk Estimates – sex, age and smoking history specific
- Model uses the known reduction in Excess Relative Risk over time from epidemiological data on smoking cessation

$$RR_{RRP}(t) = 1 + (RR_{CC}-1)\,(F + (1-F)\,\exp(-t\ln(2)/H))$$

Reduction of Risk Over Time Since Quit



Disease	RR half-life (95% CI)	# of Studies	Blocks* of Data
IHD	**4.40** years (3.26, 5.95)	23	41
Lung Cancer	**9.93** years (9.31, 10.60)	85	106
Stroke	**4.78** years (2.17, 10.50)	9	11
COPD	**13.32** years (11.86, 14.96)	11	13

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Data Sources to Support RRP Factor ("F")

Aerosol Chemistry	**Reduced Formation** of Harmful and Potentially Harmful Constituents
Non-Clinical Studies	**Reduced Toxicity and Risk** in laboratory and animal models
Clinical Studies *(Adult Smokers)*	**Reduced Exposure** to Harmful and Potentially Harmful Constituents **Reduced Risk** – favorable changes in Clinical Risk Endpoints
Behavioral Studies	**Perception and Behavioral Assessment** – perception of risk, intention to use, and actual use
Post-Market Studies *(Consumers)*	**Cross-Sectional Surveys** to assess the prevalence of RRP use **Cohort Studies** behavioral trajectories (e.g., use patterns) and risk reduction

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The Population Health Impact Model estimates the reduction in the number of smoking-attributable deaths associated with the introduction of an RRP.

It compares for a given year, the smoking-attributable mortality estimated to occur were the RRP introduced a defined number of years earlier, with the number that occurred when it was not introduced.

The difference is indicative of the population-level effect of introducing the RRP.

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Reduced Risk Products ("RRPs") is the term we use to refer to products with the potential to reduce individual risk and population harm in comparison to smoking combustible cigarettes. PMI's RRPs are **in various stages of development**, and we are conducting **extensive and rigorous scientific studies** to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke, and ultimately claims of reduced disease risk, when **compared to smoking combustible cigarettes**.

Before making any such claims, we will need to **rigorously evaluate the full set of data** from the relevant scientific studies to determine whether they substantiate reduced exposure or risk. Any such claims **may also be subject to government review and approval**, as is the case in the USA today.

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Source: Philip Morris International R&D

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