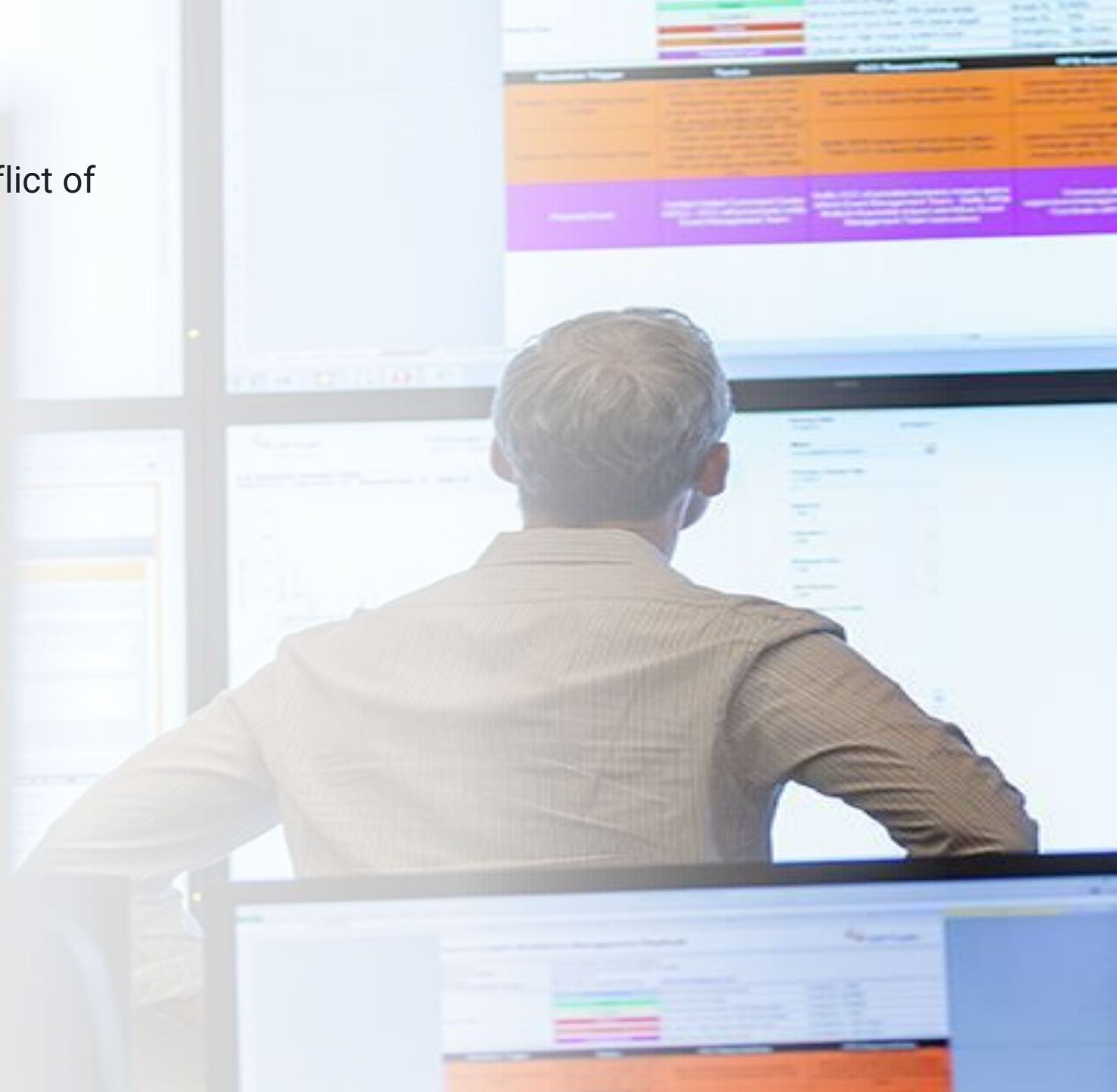


Conflict of interest statement

“The Author(s) declare(s) that there is no conflict of interest.”



USE OF ELECTRONIC HEALTH RECORDS TO UNDERSTAND DISEASE PROGRESSION IN LUPUS

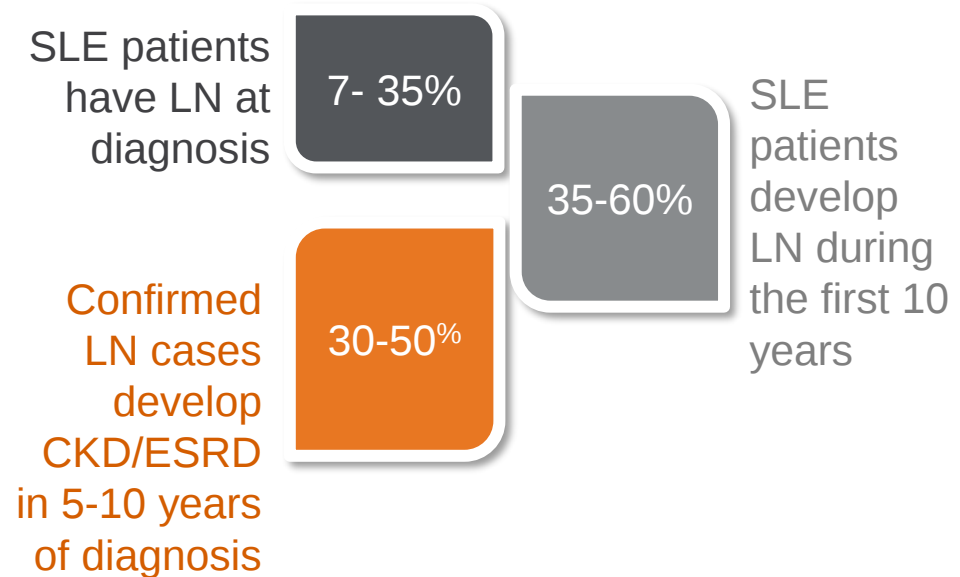
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Optum Global Solutions, Noida, India

Virtual ISPOR Europe 2021
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Background and Rationale

- Systemic Lupus erythematosus (SLE) is an autoimmune condition often leading to organ system involvement.
- Renal involvement, termed Lupus Nephritis (LN), in SLE is very common and is a major predictor of increased morbidity and mortality.
- Despite current management, a huge proportion of LN cases progress to Chronic Kidney Disease (CKD) or End Stage Renal Disease (ESRD) necessitating dialysis and/or a kidney transplant.
- Early identification and monitoring could possibly delay the progression to CKD/ESRD in SLE/LN patients.
- This study aims to assess disease progression after SLE diagnosis along with time to progression using real world data and highlight the unmet needs.



Objectives

The objective of this study is to understand the disease progression in SLE using real world data. Specifically,

- | | |
|--|--|
| <p>1 Assess the proportion of patients with SLE who develop LN</p> |  <ul style="list-style-type: none">• Proportion of patients with LN/CKD at the time of SLE diagnosis• Proportion of patients who develop LN during the follow-up period• Assess the mean/median time from SLE diagnosis to LN |
| <p>2 Assess the proportion of LN/ SLE patients who progress to CKD/ESRD</p> |  <ul style="list-style-type: none">• Assess the proportion of Patients with LN who progress to CKD/ESRD• Assess the proportion of SLE Patients without evidence of LN who progress to CKD/ESRD• Assess the mean/median time to disease progression |
| <p>3 Assess LN disease progression in patients who received treatment (CellCept)</p> |  <ul style="list-style-type: none">• Evaluate the proportion of patients receiving CellCept (MMF*)• Assess LN progression to CKD/ESRD among patients who received cellcept |

*mycophenolate mofetil

Methodology

Data Source: Optum Electronic Health Record Database; Study Period: 01/07/2016 and 31/12/2020

SLE population identification

- Patients with ≥ 2 records for lupus between 01/01/2017 and 31/12/2018; 1st record set as the first index date
- Continuous activity 6-months before and 24-months after the first Index
- No records for SLE or LN/CKD/ESRD during baseline, including the index date

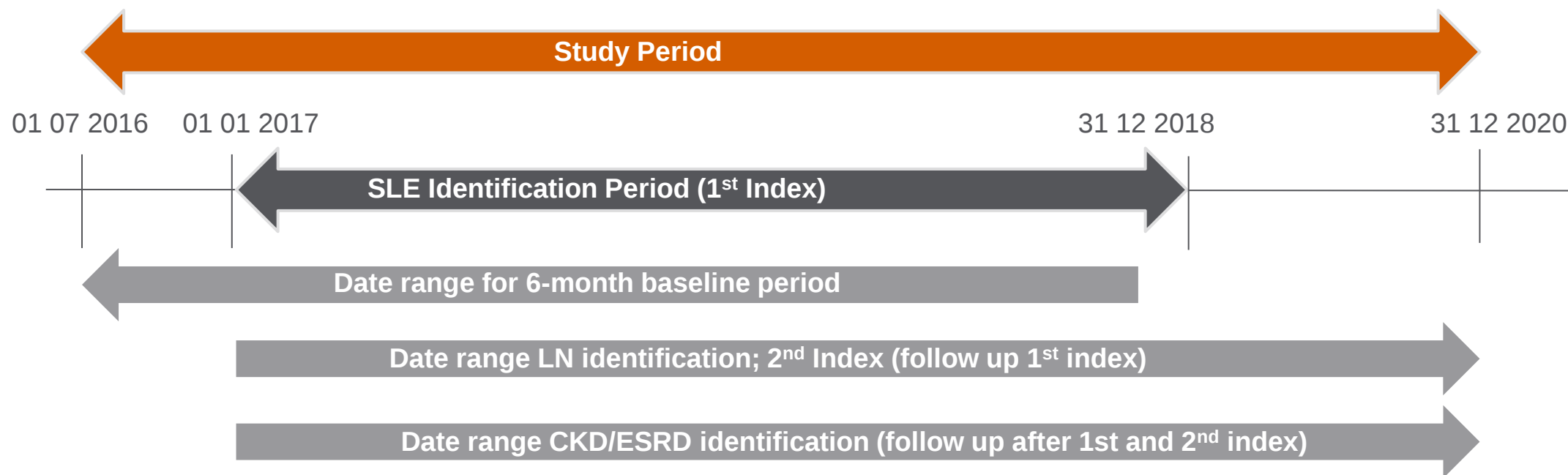
Patients with LN

- SLE patients followed after first index to assess for evidence of LN; recorded as second index date
- A subset of LN patients were identified (evidence of use of Cellcept)

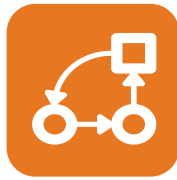
Patients with CKD/ESRD

- LN patients were tracked for a variable period of ≥ 6 months from second index to check for evidence of CKD/ESRD
- SLE patients without evidence of LN were tracked from first index for a variable period of ≥ 6 months to check for evidence of CKD/ESRD

Study Schematic and Identification Criteria



SLE: ICD 10
diagnosis codes



LN: ICD 10 diagnosis
codes for LN/symptoms
suggestive of LN



CKD/ESRD: ICD 10
diagnosis codes for
renal insufficiency



Cellcept (MMF):
NDC code/ J code

Optum Life Sciences Core Data Assets

Optum insurance claims

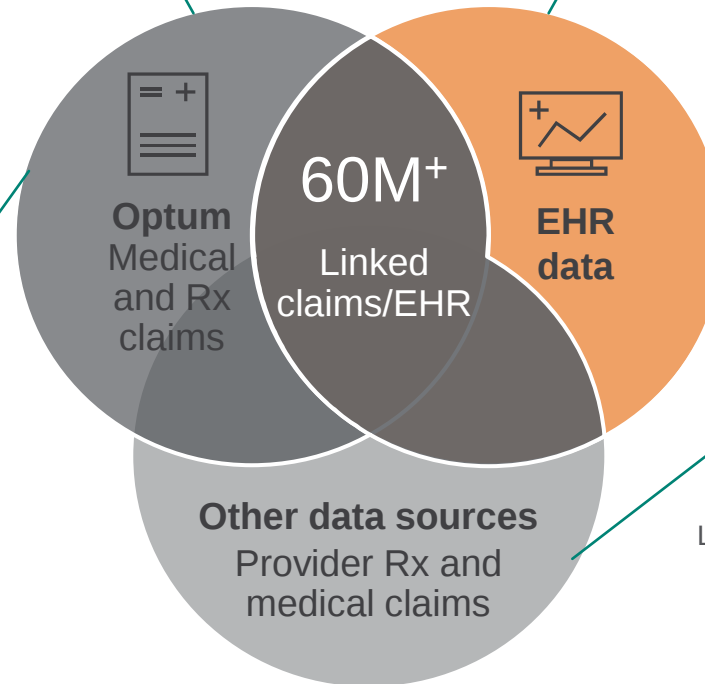
- Sourced from a single payer
- Medical and pharmacy claims
- Complete enrollment and eligibility control
- Prioritized if there are duplicates from other sources

Provider claims

- Sourced from risk sharing provider agreements
- Eligibility controlled Rx and medical claims

21M+
LINKED EHR/
CLAIMS
PATIENTS

~3.2M
LINKED EHR/
CLAIMS
PATIENTS



Provider EHR

- De-identified EHR data from ambulatory and IDN provider networks
- Nationally representative data

103M+
PATIENTS

Partner ambulatory EMR

- De-identified EHR data from ambulatory provider practices
- Denominator of Market Clarity data

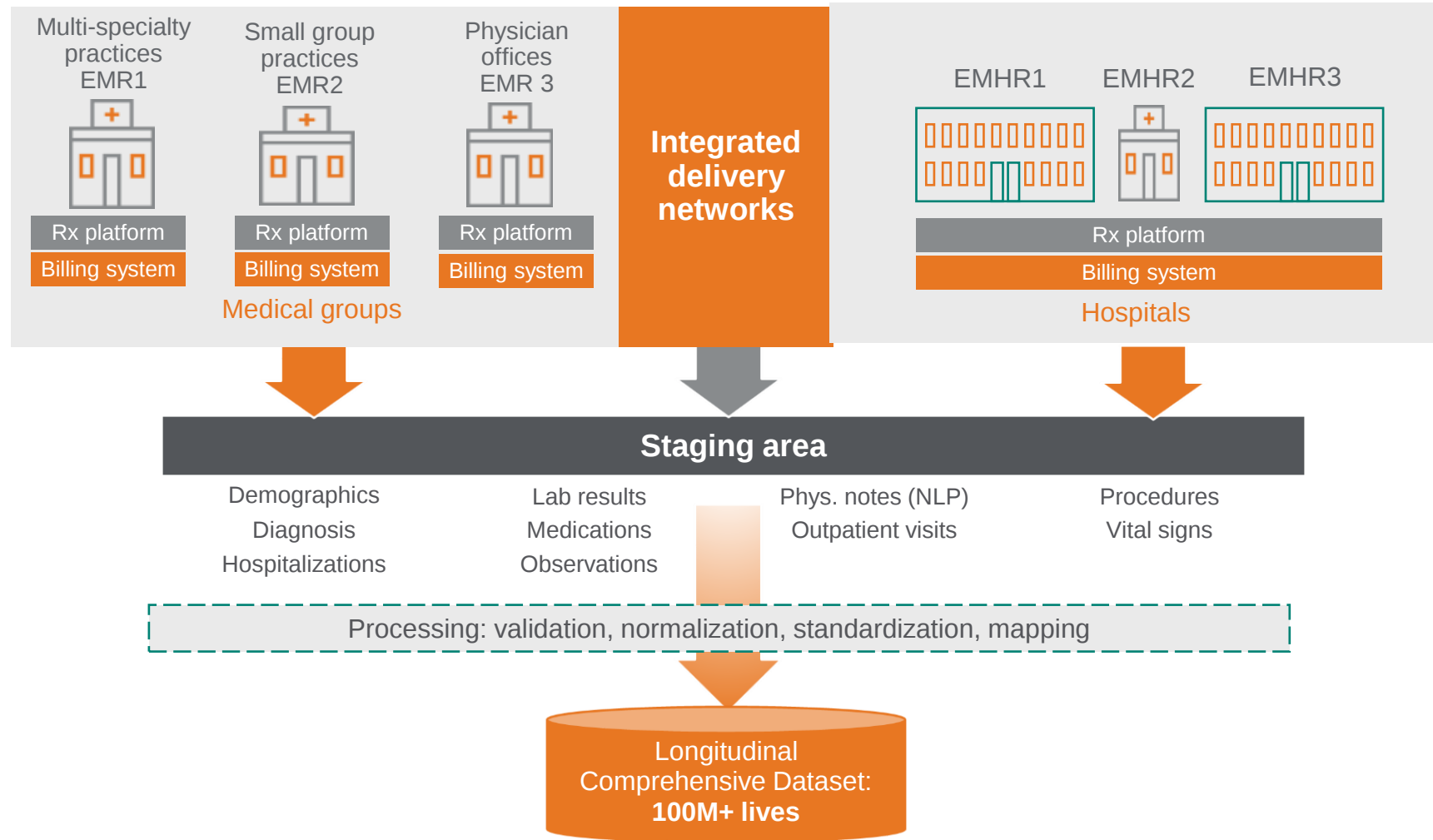
18M+
PATIENTS

Partner insurance claims

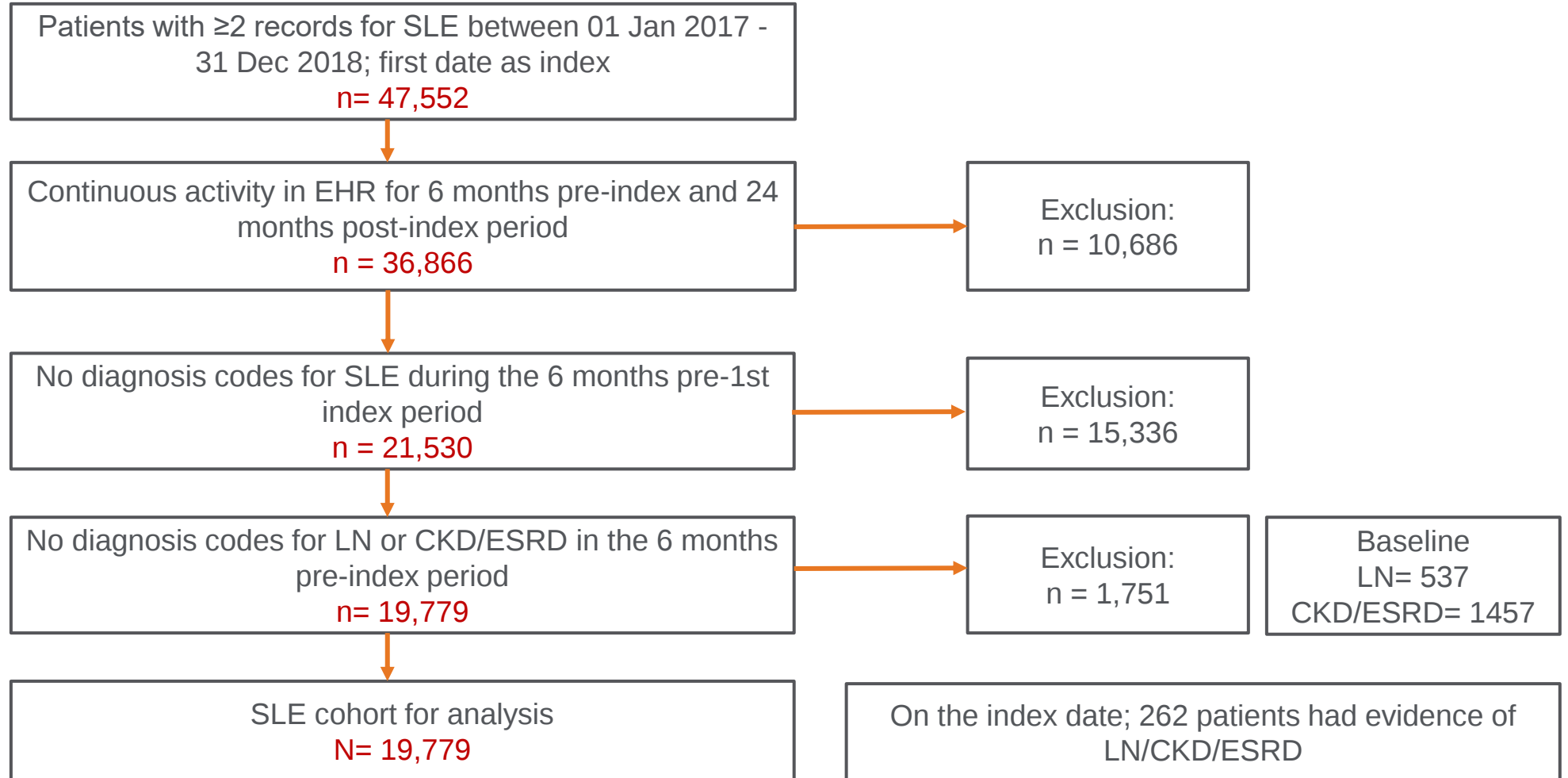
- Sourced directly from payers as well as claims clearinghouses
- Eligibility control and enrollment information

56M
LINKED EHR/
CLAIMS
PATIENTS

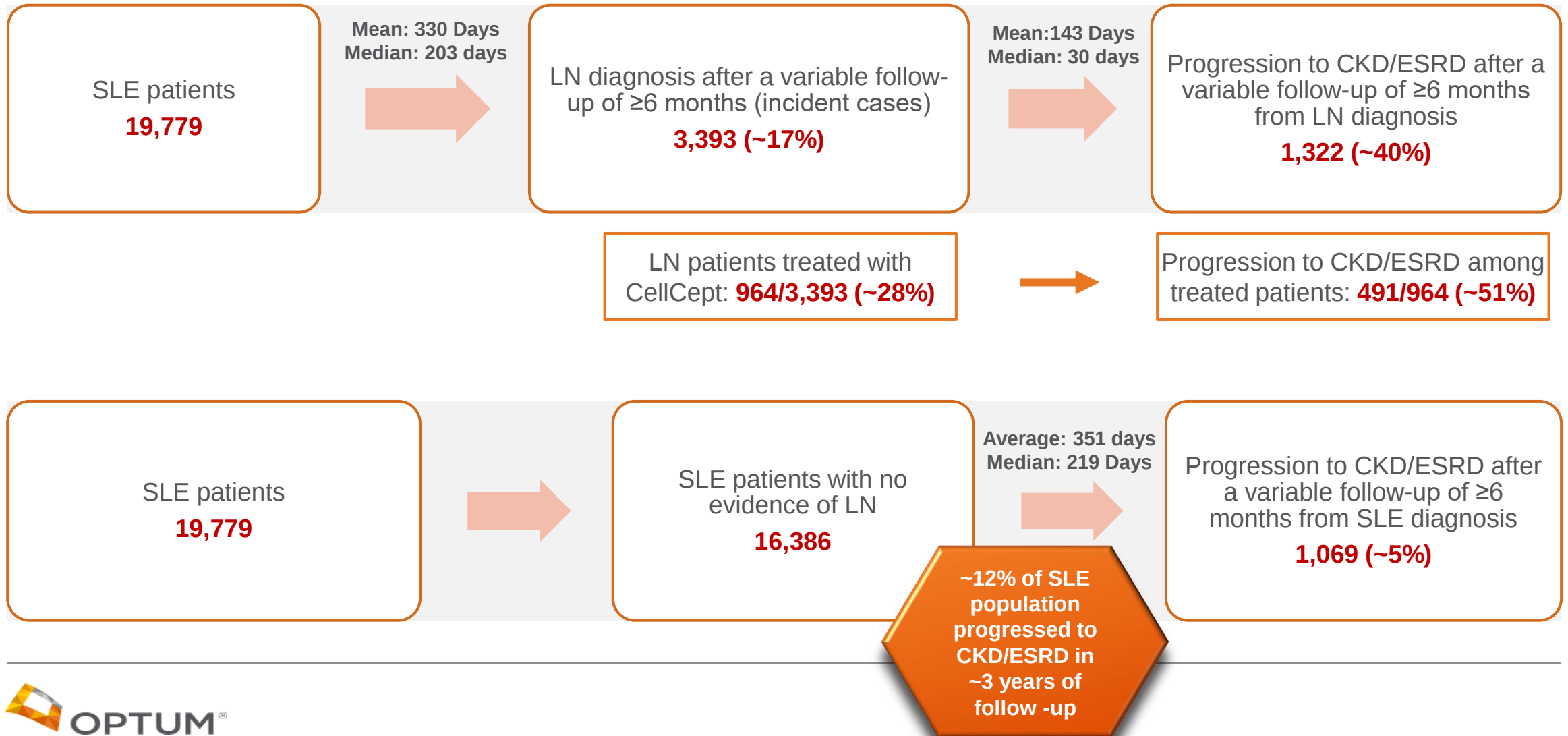
Optum Electronic Health Record (EHR) Data



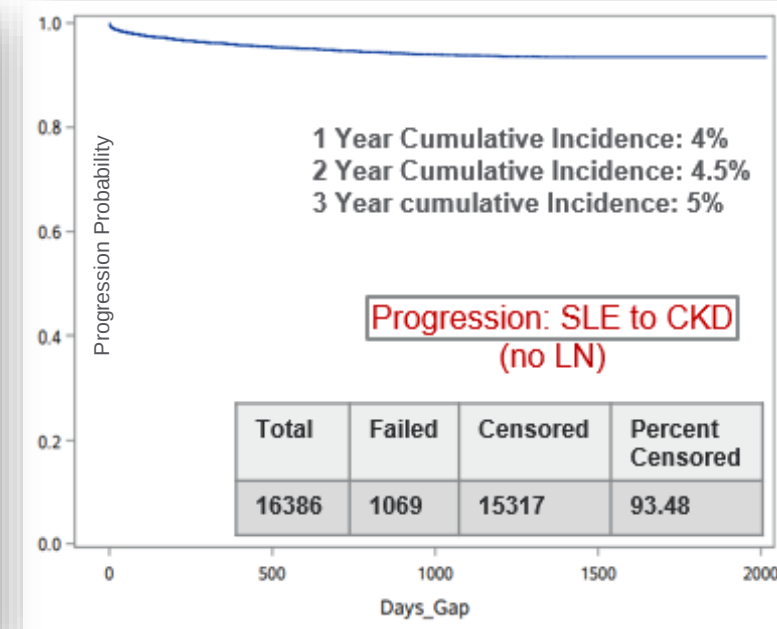
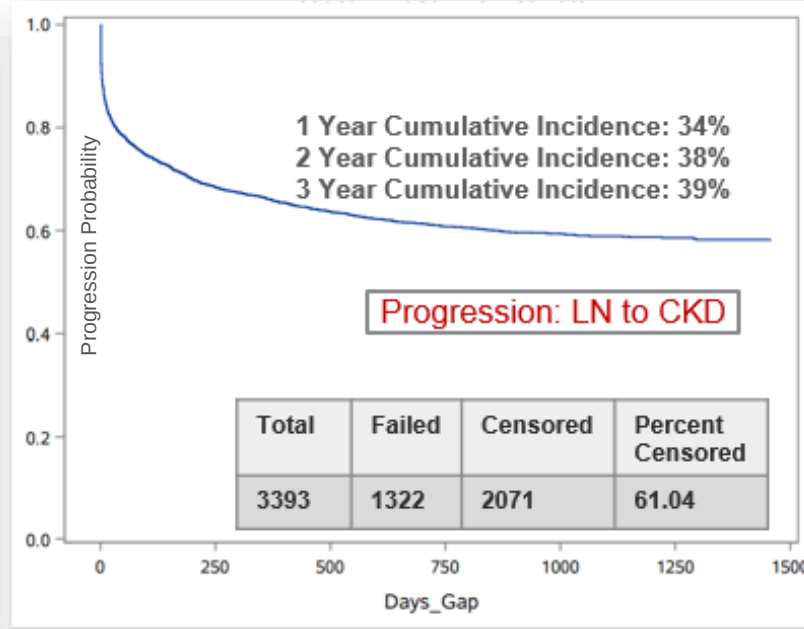
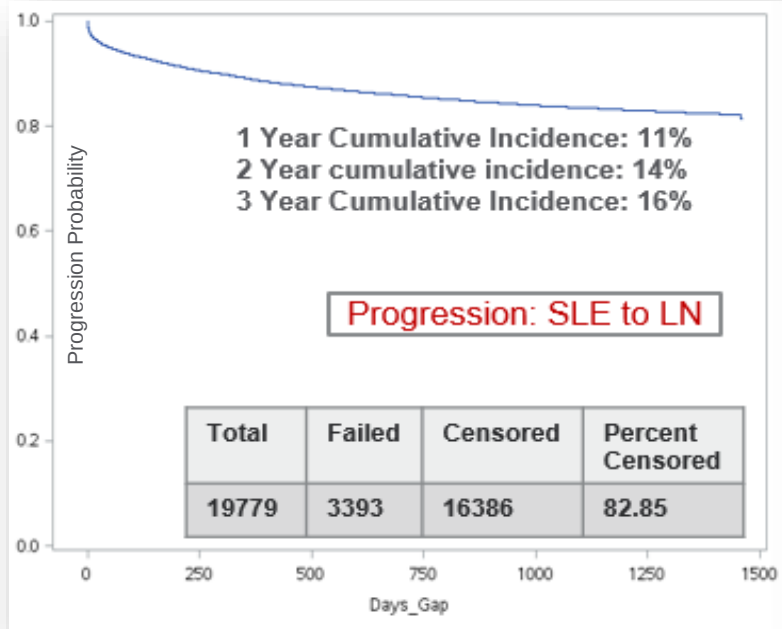
Results: Flowchart for Inclusion of Patients



Results: Disease Progression to CKD/ESRD



Results: Kaplan Meier Plots

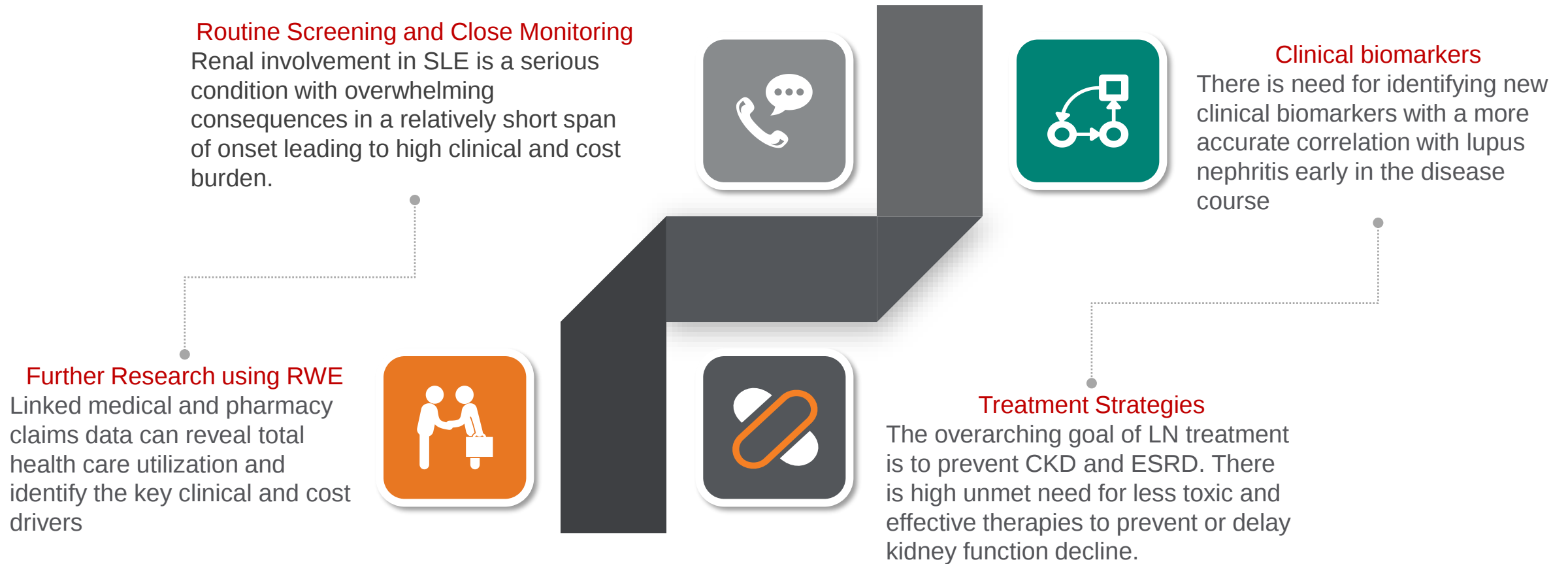


Event	Censoring
Progression to LN or CKD/ESRD	End of follow-up (31/12/2020)

The above plots suggests that lupus patients may develop LN as early as 1 year of diagnosis, and subsequently a significant proportion of patients progress to renal failure (CKD/ESRD) within a year

Implications

This study indicates a need for a more efficient SLE care trajectory



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