#### IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: INVOKANA (CANAGLIFLOZIN) PRODUCTS LIABILITY LITIGATION	: MDL NO. 2750
	JUDGE BRIAN R. MARTINOTTI JUDGE LOIS H. GOODMAN

*Document Relates to* [INSERT CASE NAME AND NUMBER]

#### **INJURY PROFILE FORM: DIABETIC KETOACIDOSIS**

Name:	DOB:
Plaintiff's Firm:	SSN:
Date of 1 <sup>st</sup> Invokana <sup>1</sup> Use:	Bates/Page # <sup>2</sup> :
Date(s) of DKA event:	Bates/Page #:
Did Plaintiff's DKA event occur prior to December 4, ☐ Yes. ☐ No.	2015?

Please confirm that Plaintiff was taking Invokana as prescribed or as provided with samples at the time of his/her DKA event:

 $\Box$  Yes, Plaintiff was taking Invokana as prescribed or as provided through samples at the time of the DKA event.

□ No.

Please identify the type of records Plaintiff has submitted contemporaneously herewith to support proof of Plaintiff's Invokana use and proof of Plaintiff's diabetic ketoacidosis event:

 $\Box$  Pharmacy |  $\Box$  Hospital |  $\Box$  Prescriber |  $\Box$  Endocrinology |  $\Box$  PCP

### [Continued to Next Page]

<sup>&</sup>lt;sup>1</sup> "Invokana" is defined to include Invokana, Invokamet and Invokamet XR.

 $<sup>^2</sup>$  In lieu of providing a Bates reference, Plaintiff may provide either: (a) a reference to the relevant PDF and PDF page number; or (b) annotated versions of the records produced with highlighting, annotation or bookmarks calling out the relevant information.

# **Records Produced Supporting Invokana Use**

Pharmacy, insurance, prescriber records, or patient assistance program records showing patient was prescribed Invokana (Bates/Page #:);		
Pharmacy, insurance, hospital records, or patient assistance program records showing use of Invokana at to the time of the DKA event <i>or</i> proof that Plaintiff had and was taking Invokana samples at the time of the DKA event (Bates/Page #:);		
Diabetes Type:   Type 1 Diabetes   Type 2 Diabetes   (Bates/Page #:)		
Pharmacy records documenting an actual fill of an Invokana prescription in the 4-week period prior to Plaintiff's DKA event (or 12-week period, for a 90-day prescription), or proof that Plaintiff was taking Invokana samples at the time of the DKA event (Bates/Page #:)		

## **Records Produced Supporting DKA Event**

Confirmed DKA diagnosis (Bates/Page #:)
Identify the relevant serum pH values here: (Bates/Page #:)
Identify the relevant CO2/HCO3 values here:
Identify the relevant anion gap values here:
Identify the relevant serum ketones values (β-hydroxybutrate or acetone) here:(Bates/Page #:)
Identify the relevant urine ketones values here:     (Bates/Page #:)

# **Severity of Injury**

Length of hospitalization: $\Box$ 1-2 days   $\Box$ 3-4 days   $\Box$ 5-6 days   $\Box$ 7+ days   $\Box$ 20+ days	
Encephalopathy (dates):	
(Bates/Page #:)	
Respiratory failure w/ intubation (dates):	
(Bates/Page #:)	
Dialysis (dates):	
(Bates/Page #:)	
Acute kidney injury / renal failure (dates):	
(Bates/Page #:)	
$\Box$ DKA-related death (death certificate <u>must</u> be produced).	

## **Medical Condition at Time of DKA Event**

Underlying infection or illness:(Bates/Page #:)		
☐ Major trauma, surgery, or cardiovascular event in week prior to DKA event (type and dates):		
(Bates/Page #:)		
Chronic alcohol abuse:	(Bates/Page #:)	
Chronic drug abuse:	(Bates/Page #:)	
□ Strenuous physical activity or exercis (Bates/Page #:)	se preceding DKA:	

## **ATTESTATION**

The undersigned have reviewed and completed this Injury Profile Form in good faith.

Date:

[INSERT PLAINTIFF NAME]

Date:

[INSERT ATTORNEY NAME & FIRM INFORMATION]