

Harmonisatie

Cas Weykamp

SKML Sectie Humorale Immunologie

Congres "De Waarde van de Expert" 9 juni 2015

Patient

Arts

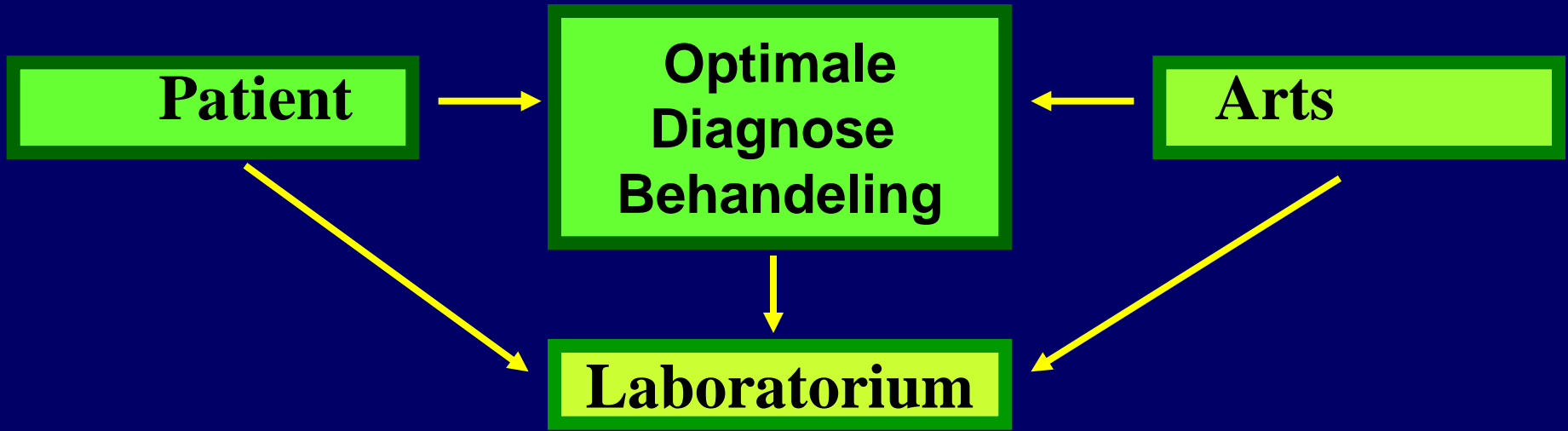
Patient

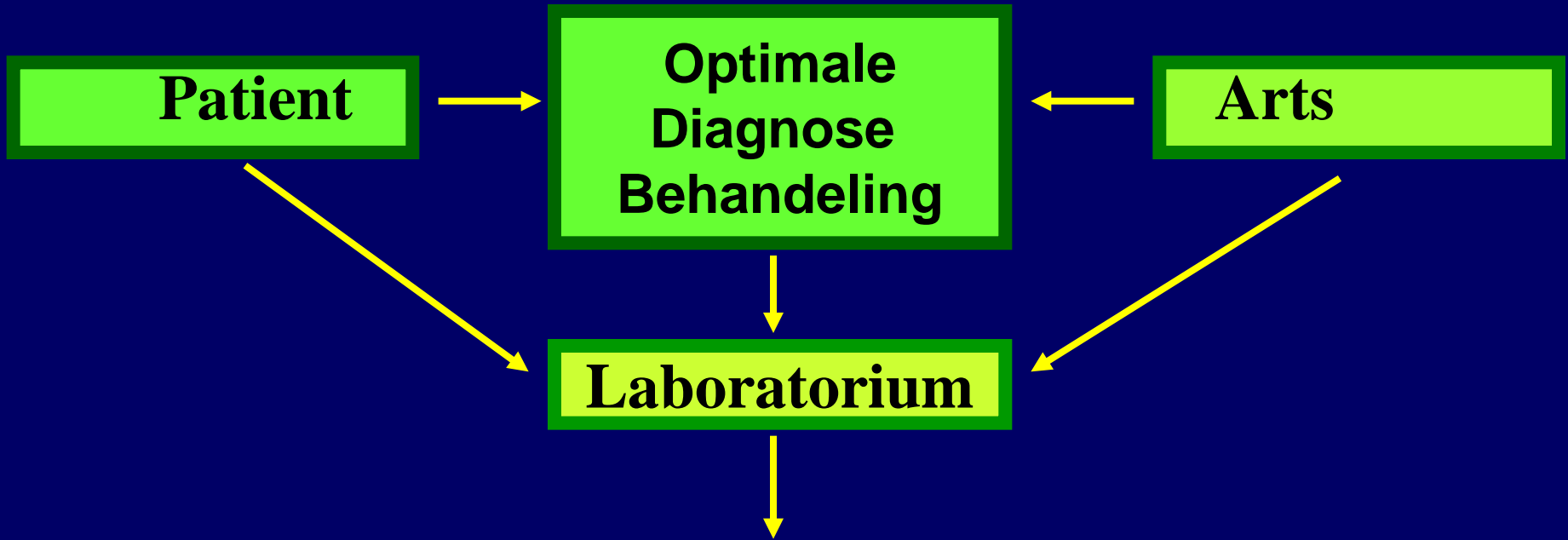


**Optimale
Diagnose
Behandeling**

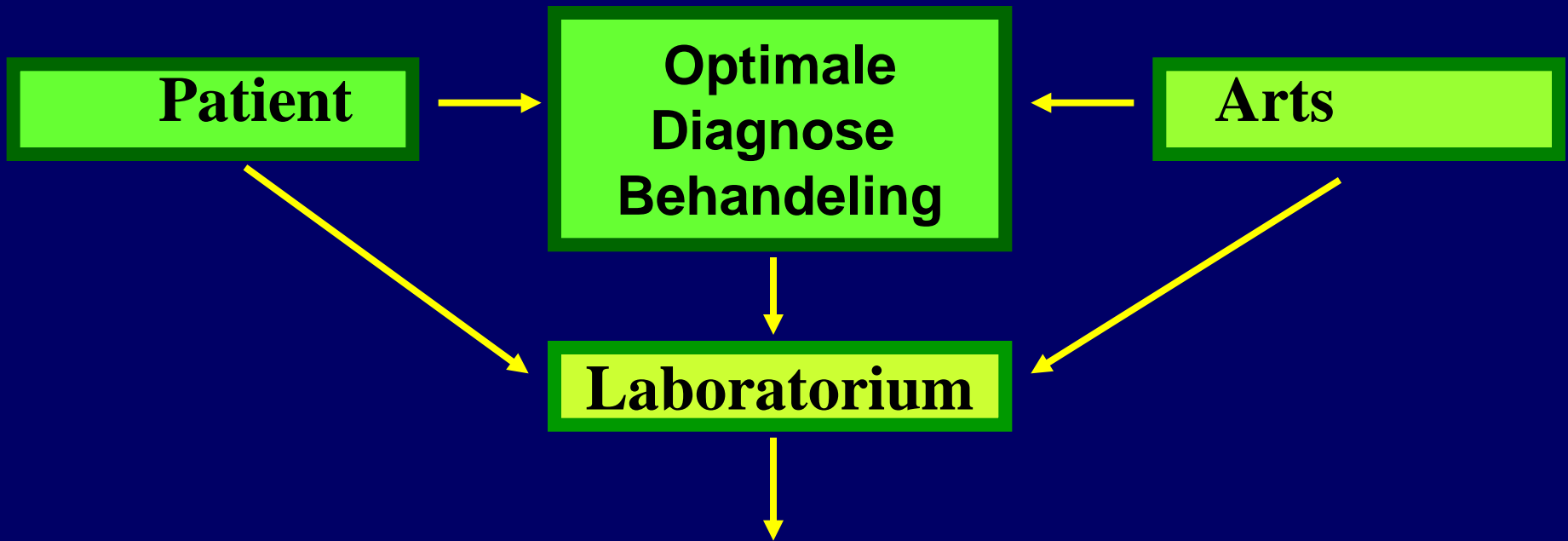


Arts





**Optimale Diagnose & Behandlung
= Optimale Laboratorium Test:**



**Optimale Diagnose & Behandeling
= Optimale Laboratorium Test:**

- Zelfde Uitkomst
- Zelfde Referentiewaarden
- Zelfde Beslisgrenzen
- Zelfde Literatuur

Patient



**Optimale
Diagnose
Behandeling**



Arts

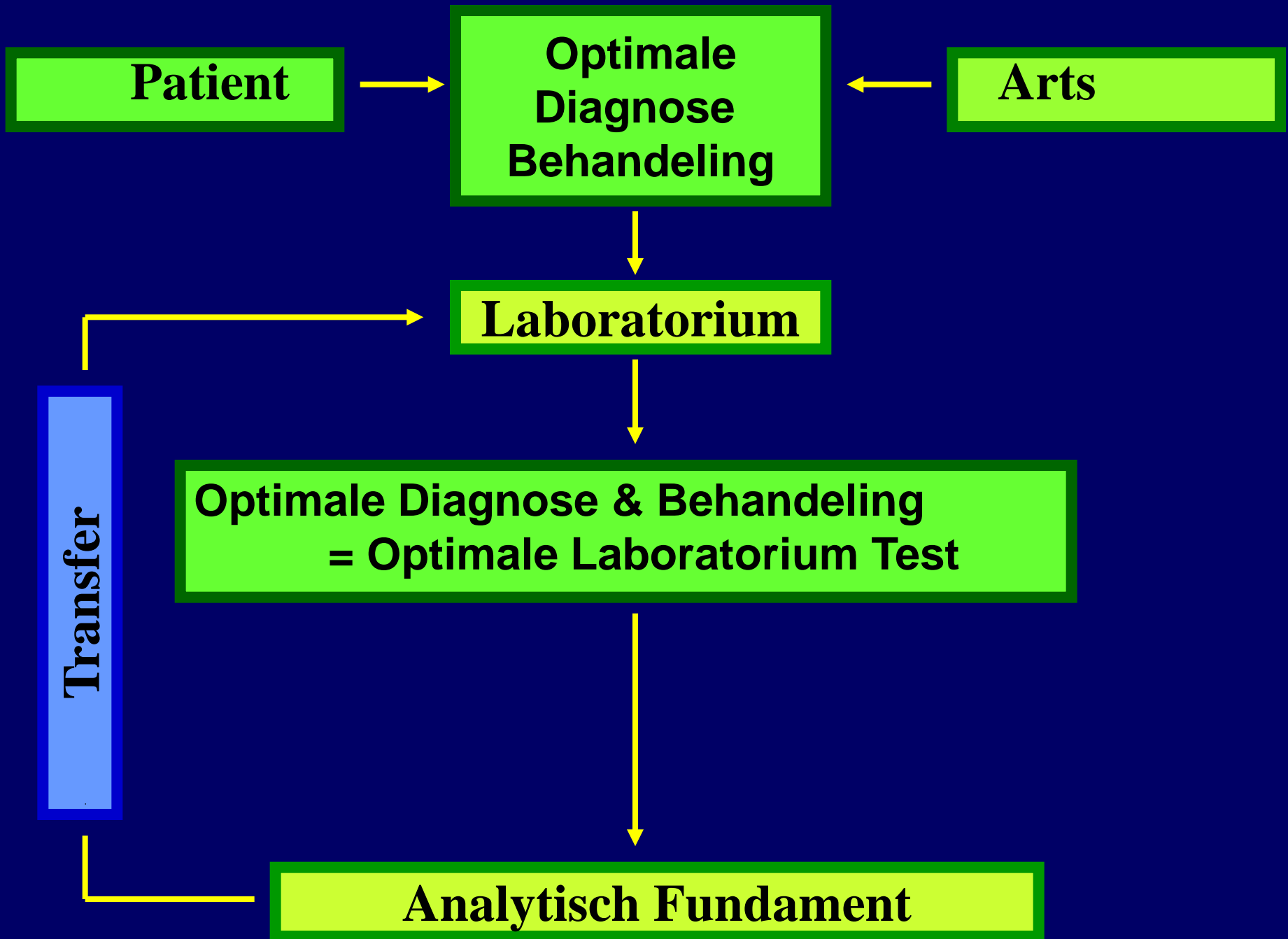
Laboratorium

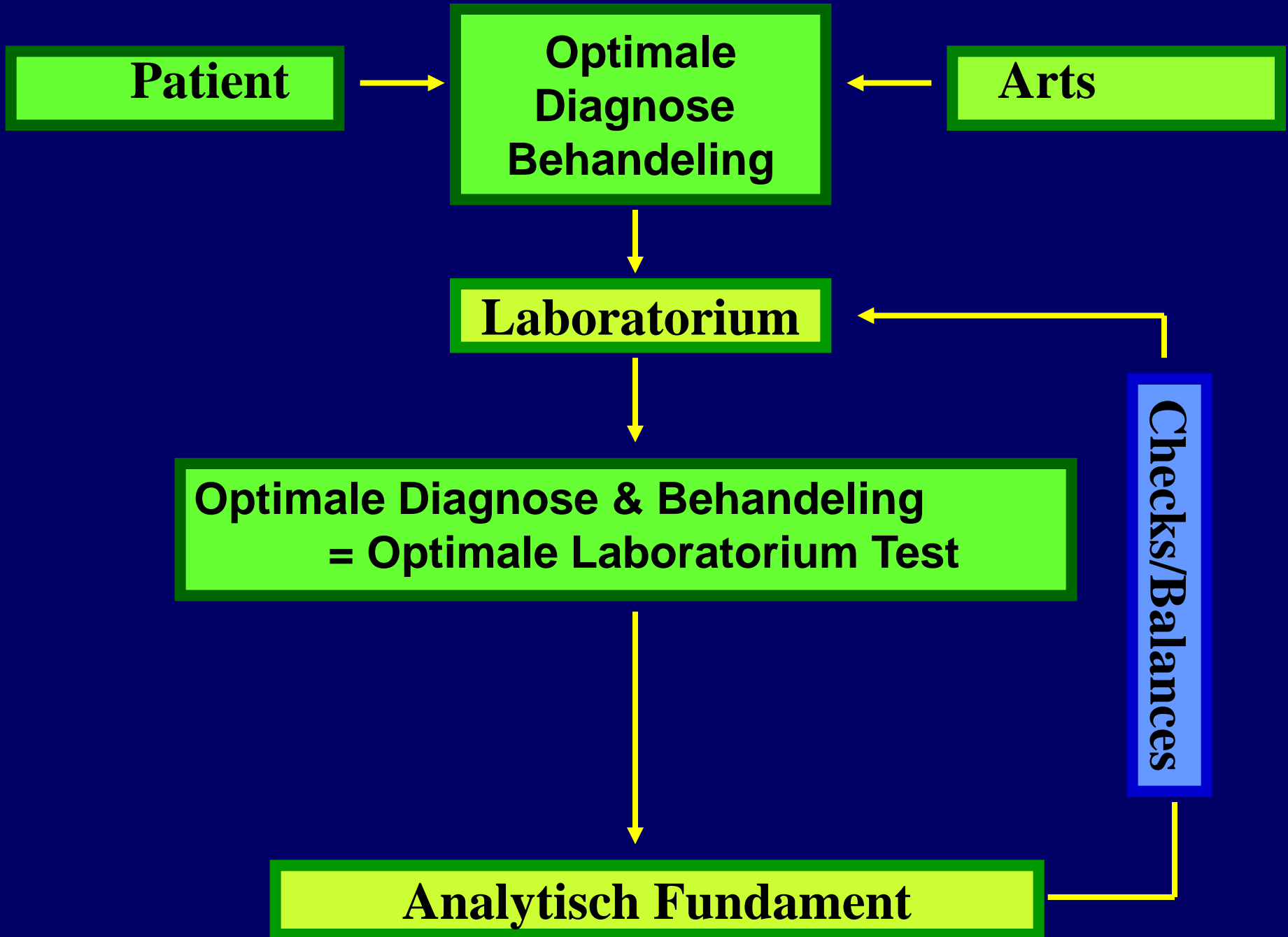


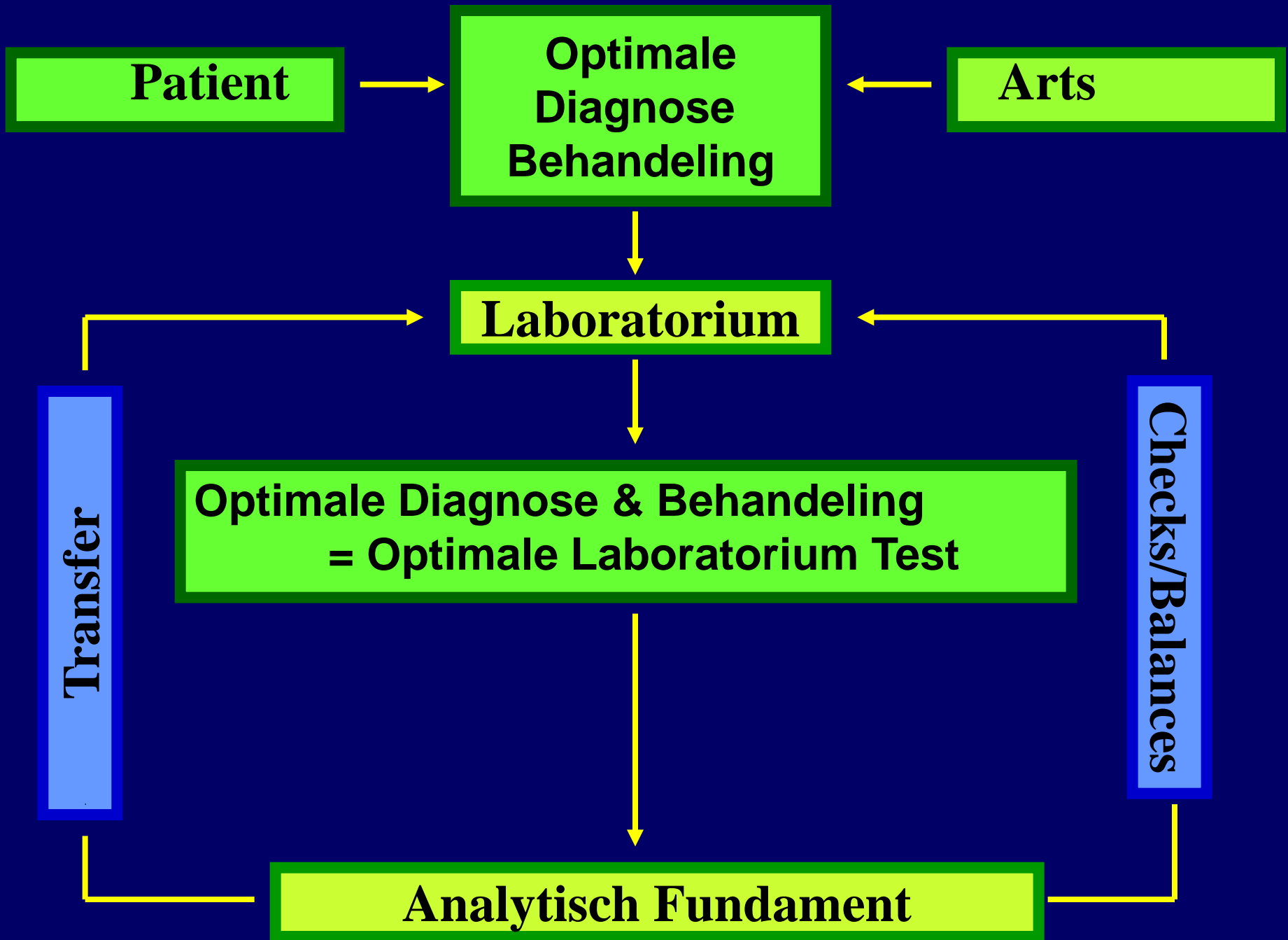
**Optimale Diagnose & Behandeling
= Optimale Laboratorium Test**



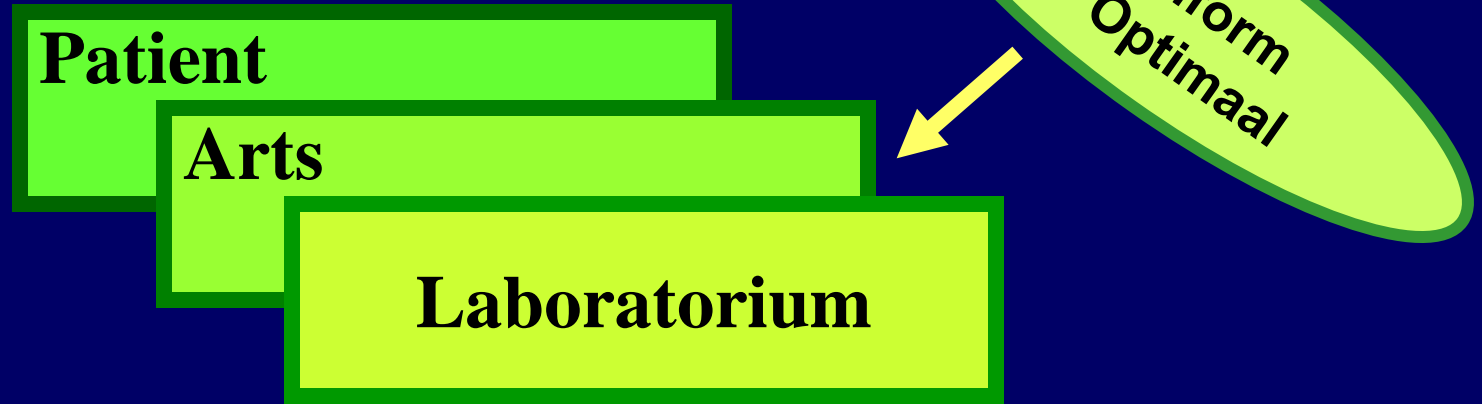
Analytisch Fundament





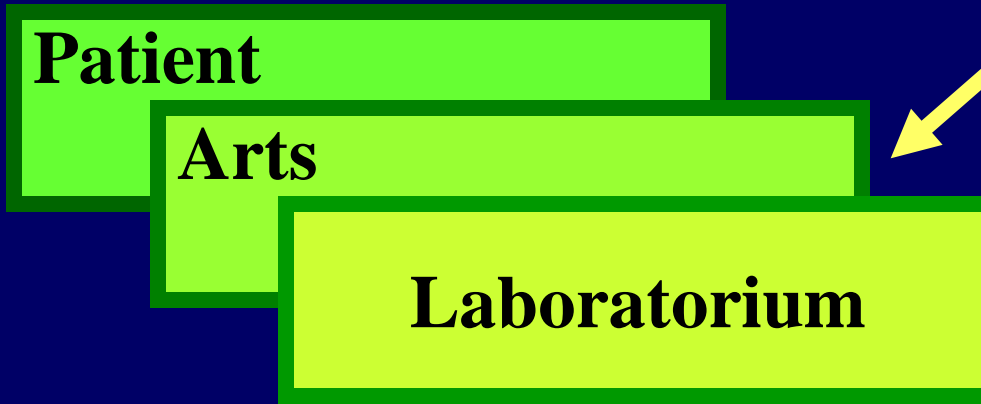


Optimale Laboratorium



**Analytisch
Fundament**

Optimale Laboratorium

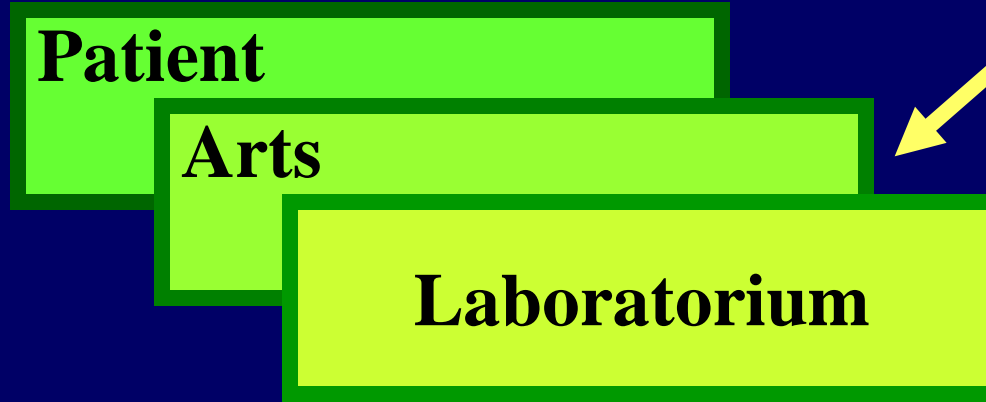


Uniform
= Optimaal

Transfer

Analytisch
Fundament

Optimale Laboratorium

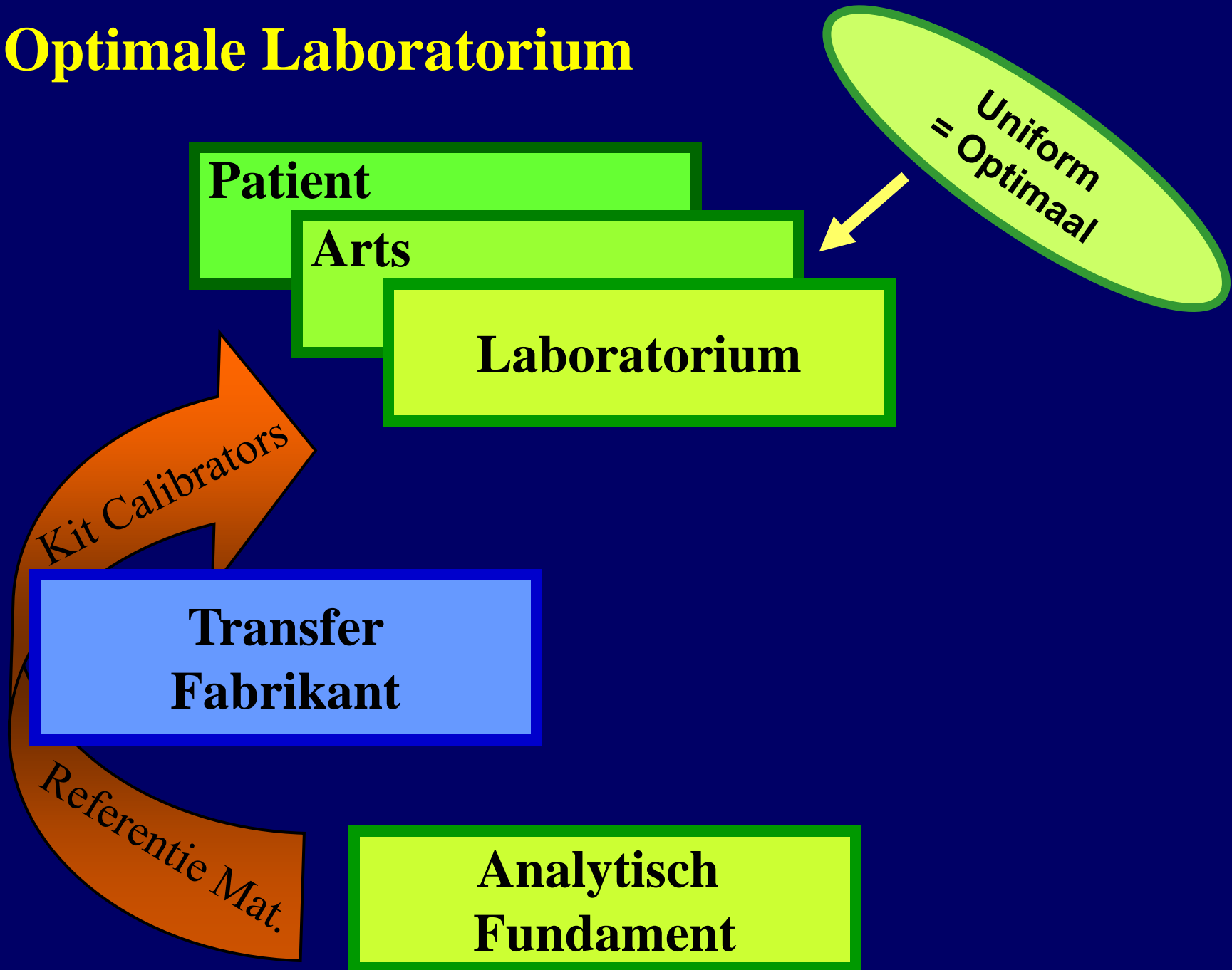


Uniform
= Optimaal

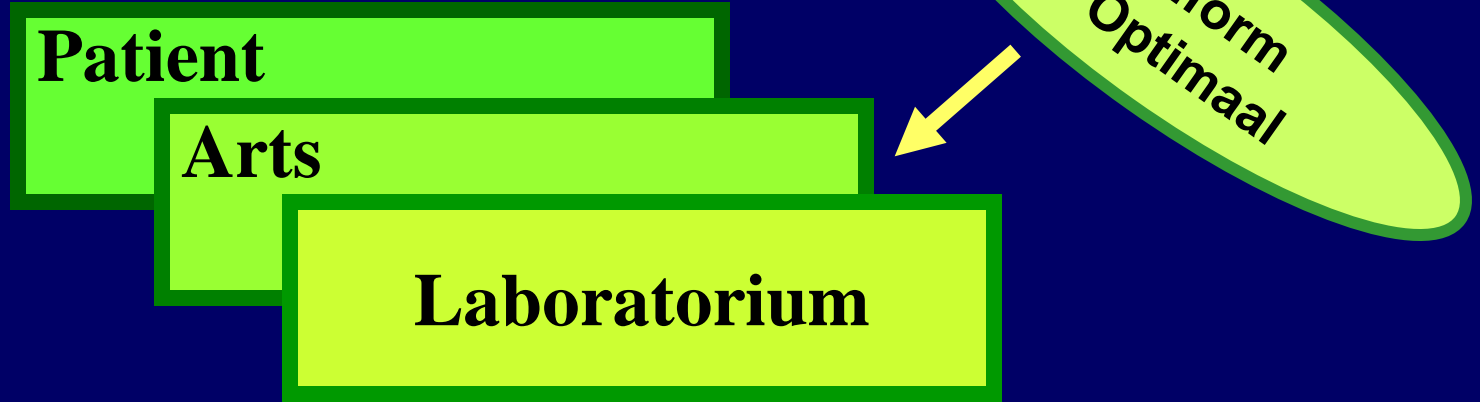
Transfer
Fabrikant

Analytisch
Fundament

Optimale Laboratorium



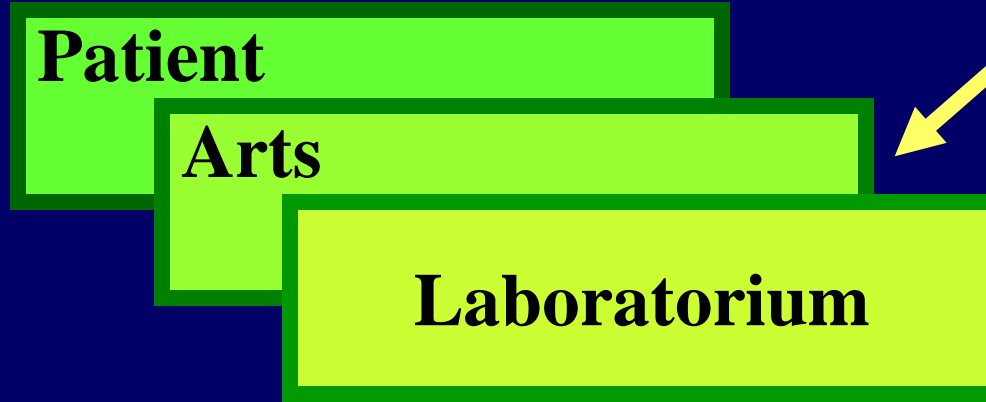
Optimale Laboratorium



Checks/Balances

Analytisch
Fundament

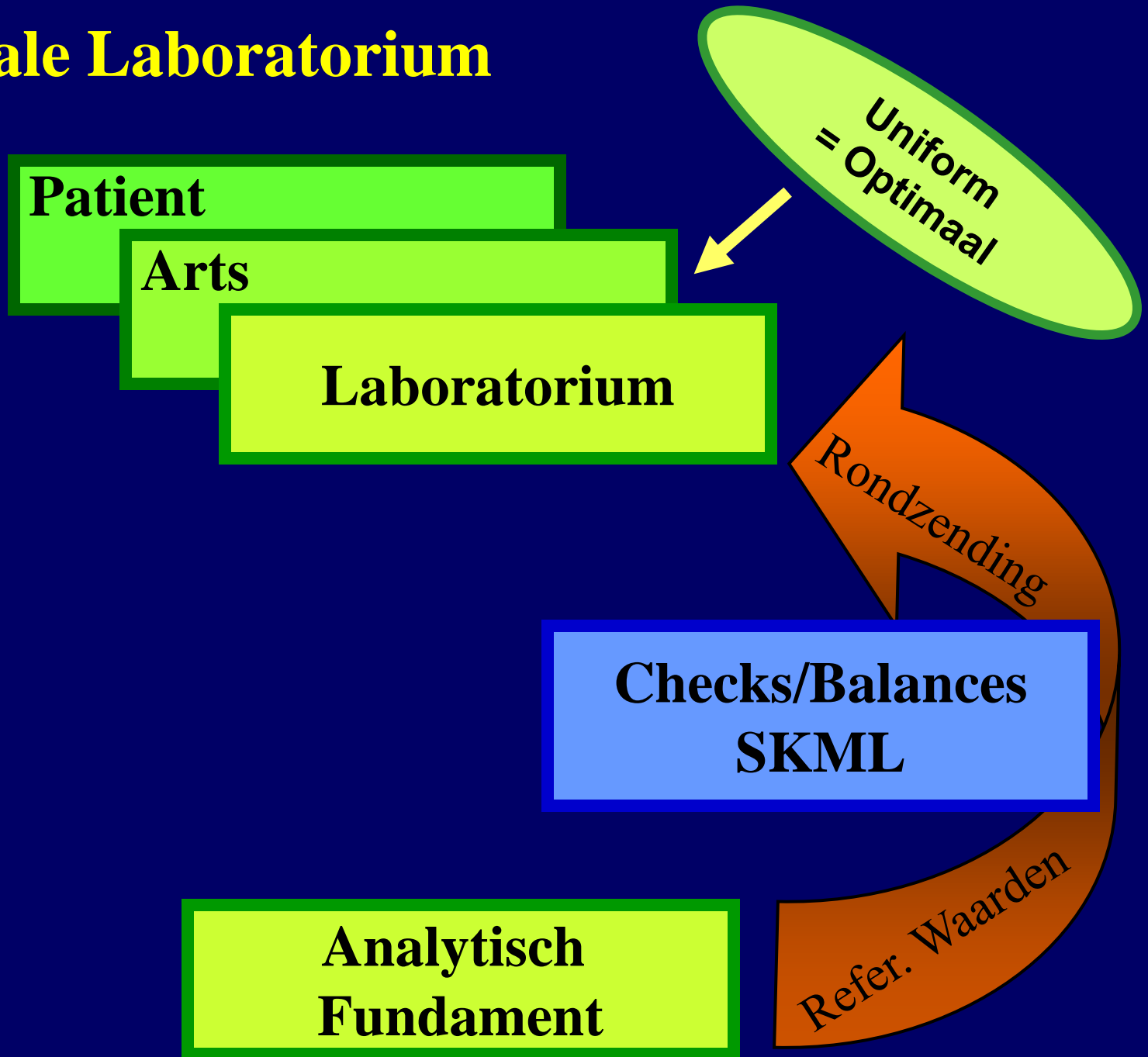
Optimale Laboratorium



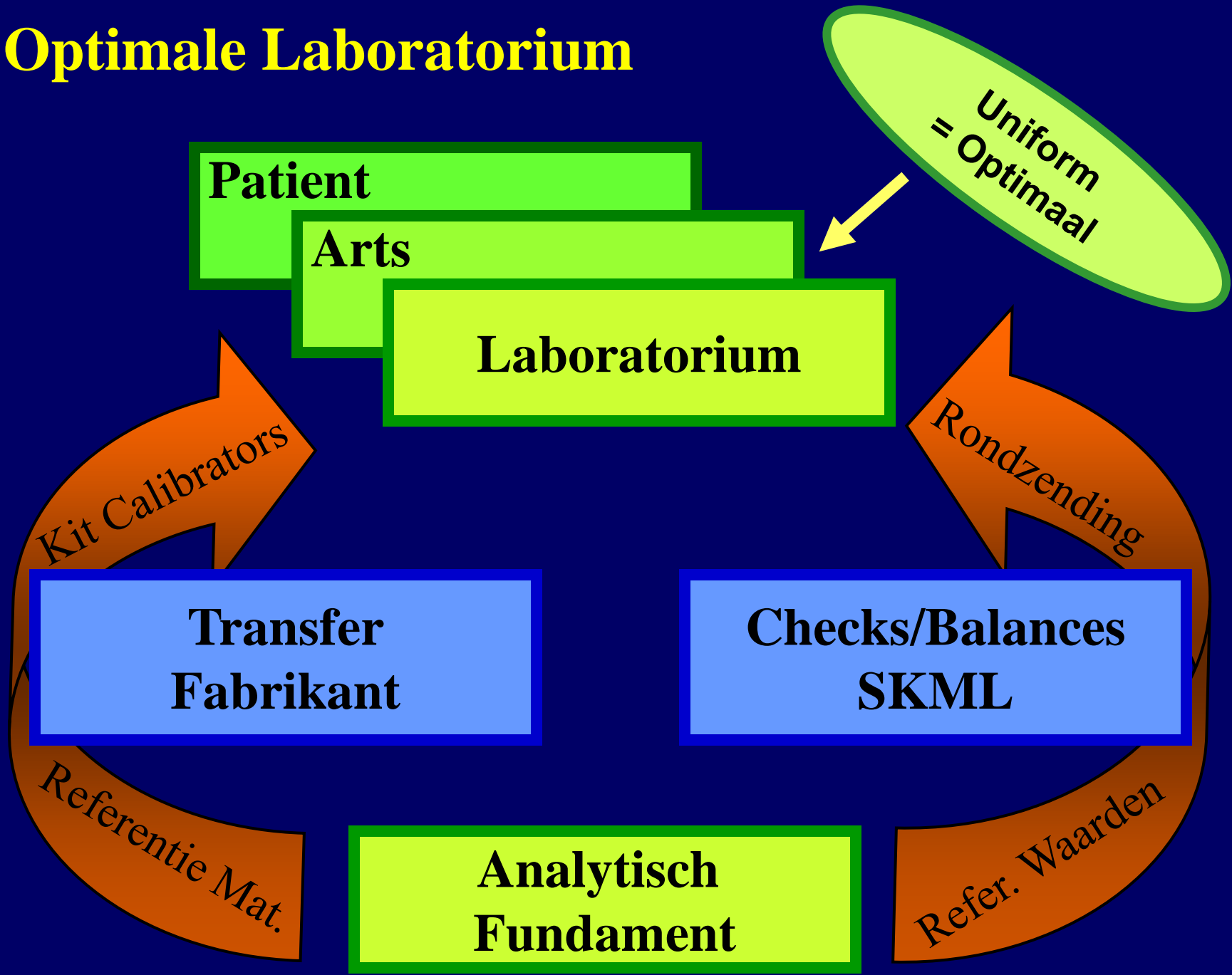
Checks/Balances
SKML

Analytisch
Fundament

Optimale Laboratorium



Optimale Laboratorium



Optimale Laboratorium

Analytisch Fundament

- Referentie Methode
 - Referentie Materiaal
 - Wereldwijde Erkenning
 - Wereldwijd Gebruik
- door Rondzenders
door Fabrikanten

Analytisch Fundament

Standardize if possible

**Harmonize if
standardization is not
possible**

Traceability of Laboratory Results

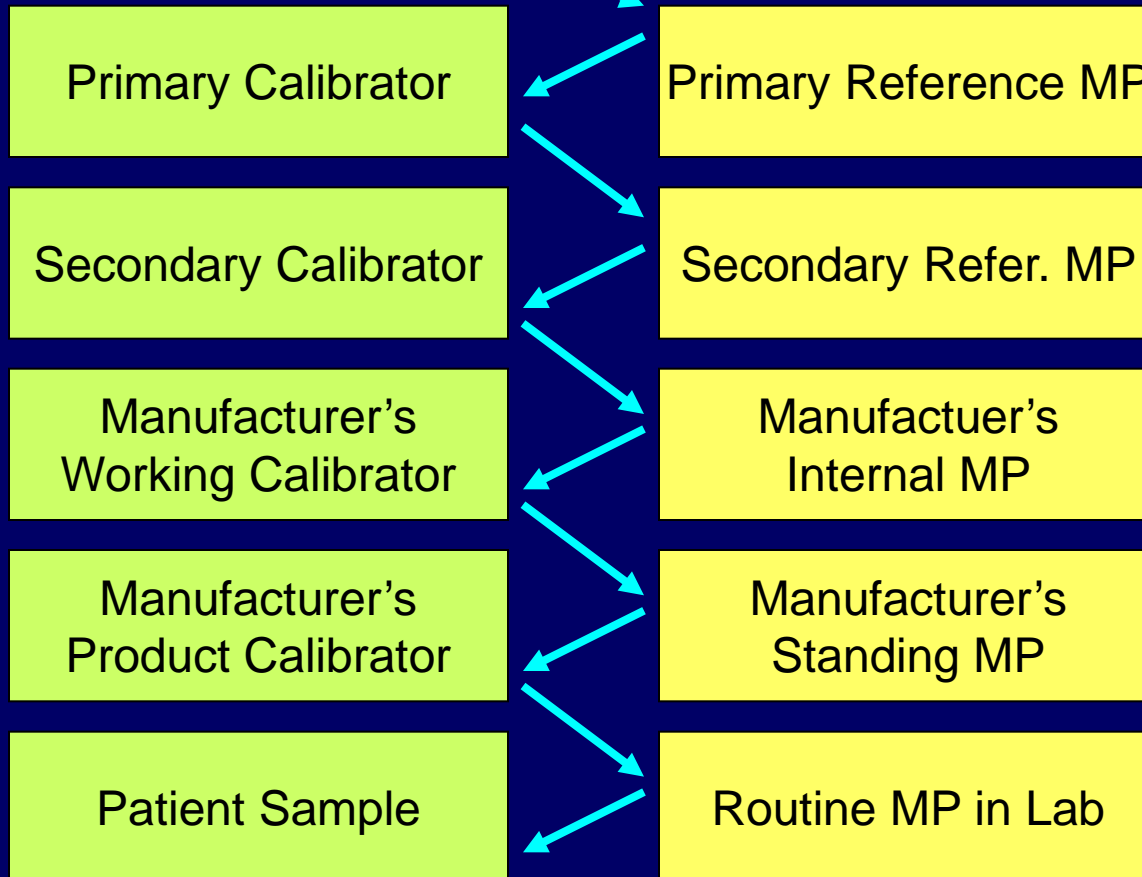
Differences between harmonization and standardization

Ø **Harmonization**: all measurement procedures get the same result for a sample when there is no reference measurement procedure (RMP)

Ø ***Standardization***: all measurement procedures get the same result for a sample and the result is traceable to SI with a RMP

Traceability Chain

Definition of the Analyte



Standardization

Interpretation
Patient Result

ISO 17511: Metrological traceability of values assigned to calibrators and control materials

Standardization

Category	Reference measurement procedure	Primary (pure substance) reference material	Secondary (value assigned) reference material ^a	Examples
1	Yes	Yes	Possible	Electrolytes, glucose, cortisol
2	Yes	No	Possible	Enzymes
3	Yes	No	No	Hemostatic factors
4	No	No	Yes	Proteins, tumor markers, HIV ^b
5	No	No	No	EBV ^c , VZV ^d

Harmonization

SKML en Standaardisatie/Harmonisatie

Draagt Internationaal bij aan Ontwikkeling

- IFCC (HbA1c – CDT)
- AACCC (Harmonization Initiative)

Past het toe in de Rondzendingen

- Combi Algemene Chemie (2005)
- Combi Immuno Chemie (2014)

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Combi Algemene Chemie

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Harmonization

Combi Immuno Chemie

ISO 17511: Metrological traceability of values assigned to calibrators and control materials

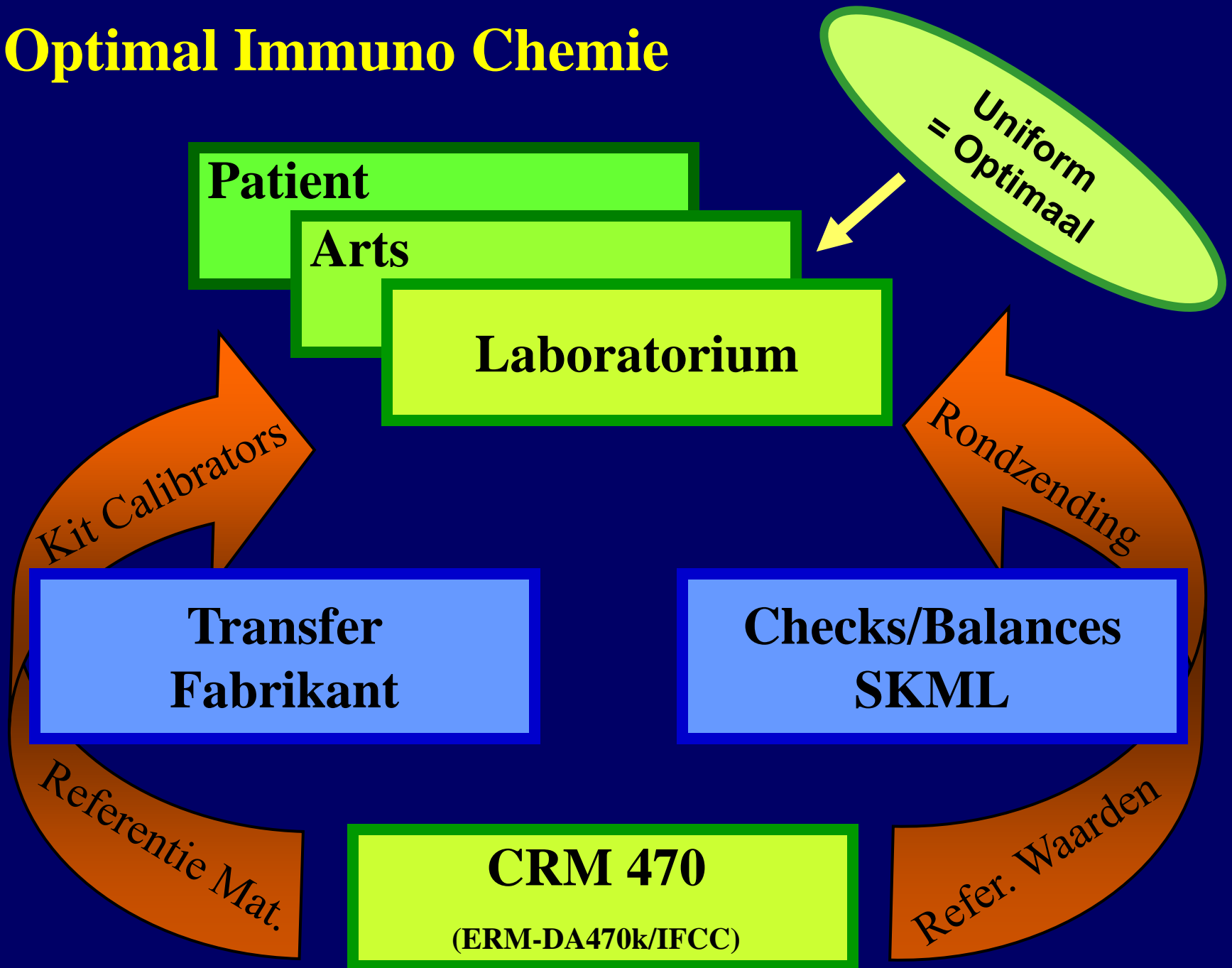
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Harmonization

Combi Immuno Chemie

Optimal Immuno Chemie



Optimale Immuno Chemie

Patient

Arts

Uniform
= Optimaal

Analytisch Fundament

- Referentie Methode?
- Referentie Materiaal?
- Wereldwijde Erkenning?
- Wereldwijd Gebruik
 - door Rondzenders?
 - door Fabrikanten?

Optimale Immuno Chemie

Patient

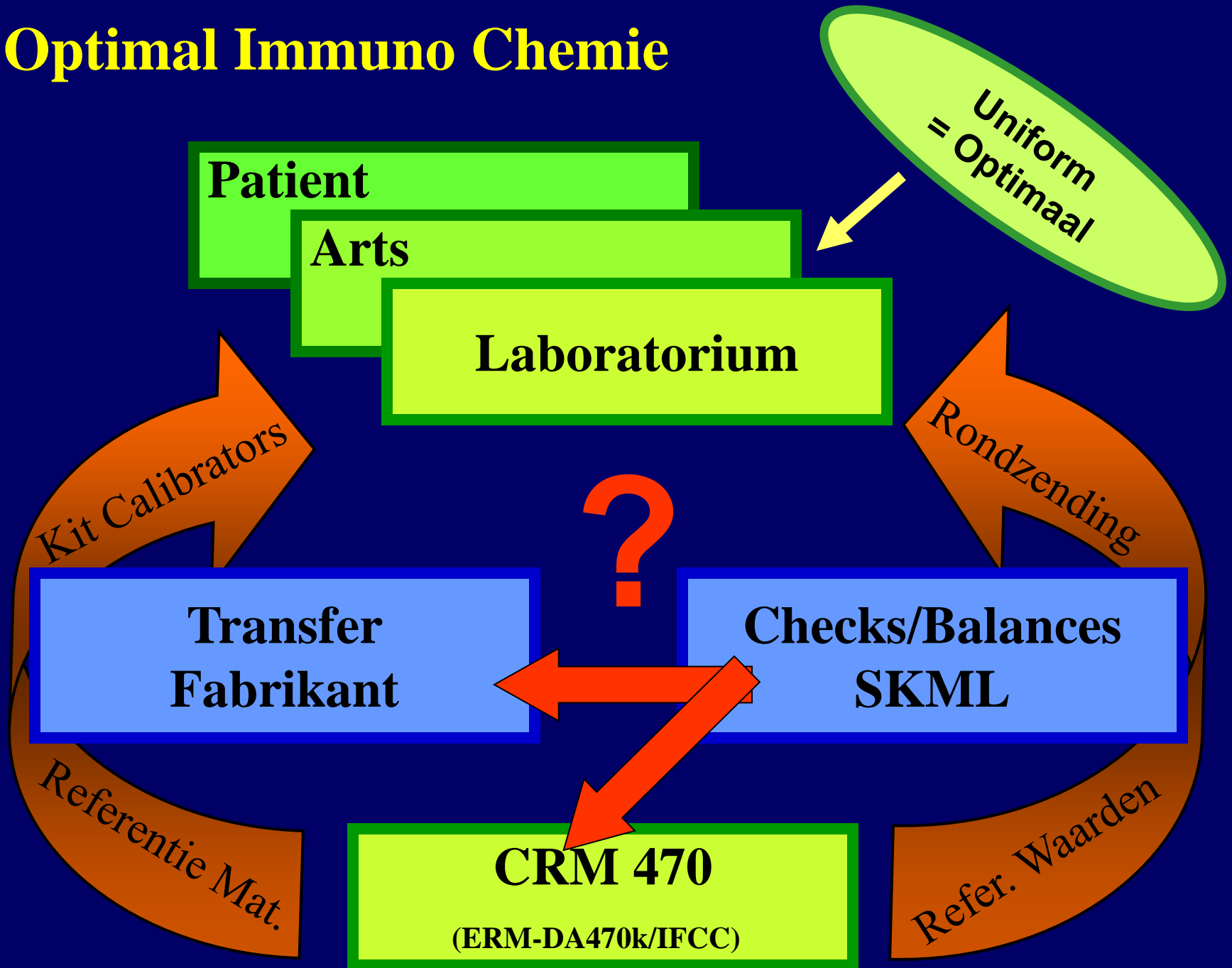
Arts

Uniform
= Optimaal

Analytisch Fundament

- Referentie Methode? Arb. (IRMM)
- Referentie Materiaal? Ja (CRM 470)
- Wereldwijde Erkenning? Ja
- Wereldwijd Gebruik
 - door Rondzenders? SKML 2014
 - door Fabrikanten? Nou.....

Optimal Immuno Chemie



**Bedankt voor
Uw Aandacht**