BIA Separations
Izkušnje slovenskega partnerja v evropskih projektih
Projekt INTENSO

Dr. Nika Lendero Krajnc

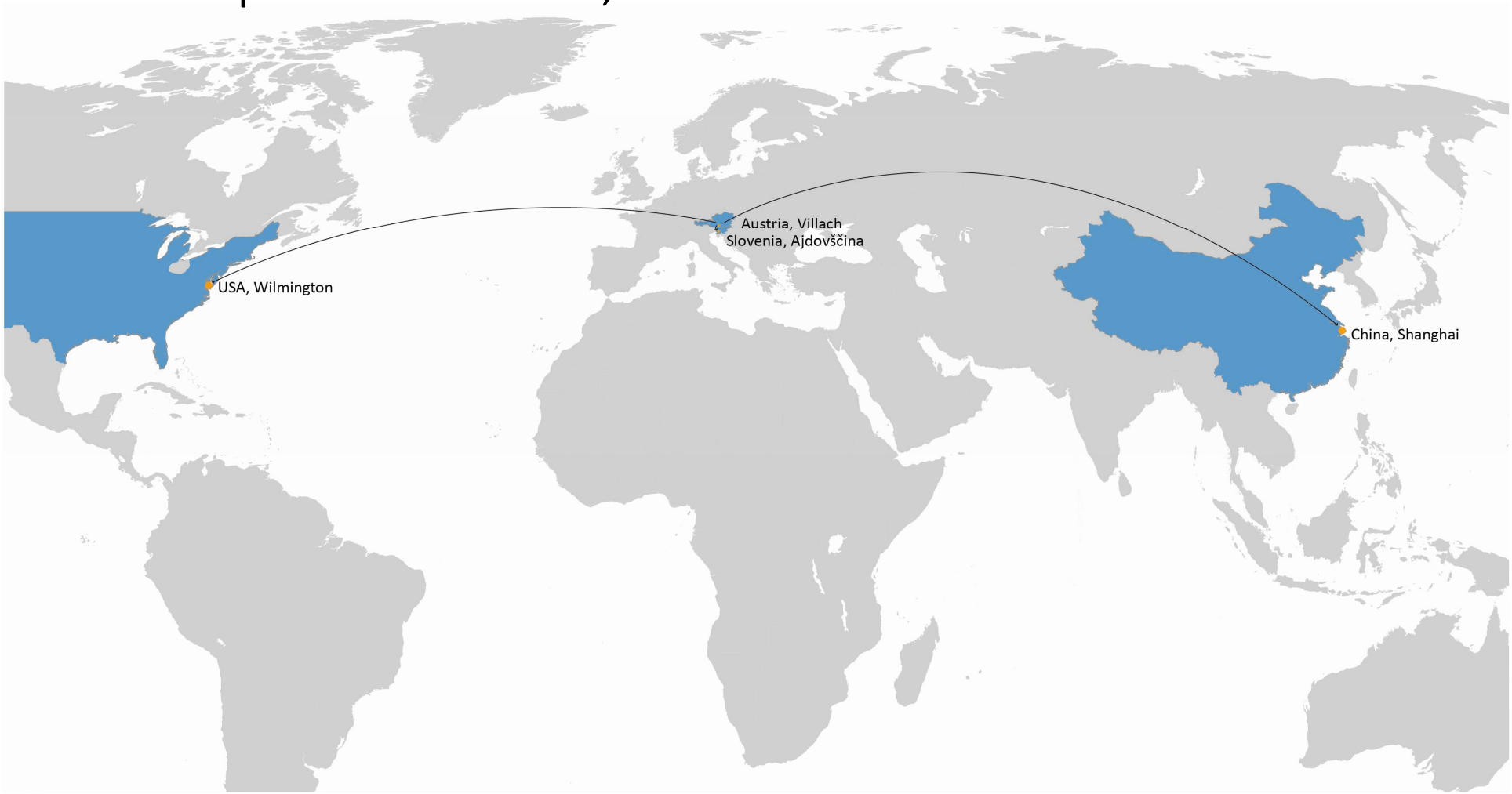
Ljubljana, 19. december 2013

BIA separations

BIA Separations

Leaders in Monolith Chromatography

- BIA Separations was founded in September 1998.
- Headquarters in Austria, R&D and Production in Slovenia.



BIA Separations

Leaders in Monolith Chromatography

- BIA Separations was founded in September 1998.
- Headquarters in Austria, R&D and Production in Slovenia.
- BIA Separations USA established in September 2007 - sales and tech support office.
- BIA Separations China established in January 2011 - sales and tech support office.
- More than 85 employees world wide.
- Pioneers and leaders in proprietary monolithic technology (Convective Interaction Media CIM®). 4 USA patents granted including their foreign equivalents, more pending.

BIA Separations

Main focus:

To develop and sell methacrylate monolithic columns & develop methods and processes for large biomolecules separation and purification.

BIA Separations
Experties

- At the moment more than 70 employees:
  - more than 25 researchers
  - 17 PhDs
- We accumulate the knowledge in the following fields:

  chemistry, polymerization, chemical technology, solid phase synthesis, biochemistry, biotechnology, molecular biology, microbiology, physical chemistry, ...
- The R&R infrastructure includes suitable chemical and manufacturing labs together with biological safety level 2 laboratory.

BIA Separations
Important Milestones

- 2004: **First monolith used for the industrial cGMP purification for plasmid DNA at Boehringer Ingelheim provide 15-fold increase in productivity**
- 2006: **First cGMP production of a vaccine (influenza) using CIM®**
- 2008: *OEM Partnership with Agilent Technologies – develop and produce analytical monolithic columns*
- **In 2011 BIA Separations was awarded by KAPPA-Health as a model SME in the EU Co-funded research projects**

Kappa Health

- 2012: *co-marketing and co-development agreements with JSR and SDK*
- **2012: Strong R&D partner in EU projects – currently involved in three FP7 projects (http://cordis.europa.eu/)**
- 2012: Launch new line of multiuse disposable units CIMmultus.

BIA Separations

Producer of CIM® Monolithic Chromatographic Columns

CIMac Analytical Columns

CIM Disks

CIM 1 mL Tube Monolithic Columns

CIM cGMP Tube Monolithic Columns (stainless steel housing)

0.1 | 0.34 | 1 | 8 | 80 | 800 | 8000 ml

CIMmultus (multi-use disposable columns)

Kako pripraviti uspešen projekt?

Prava izbira teme:

- nekaj, kar je trenutno zanimivo in predstavlja trenutni problem oz. izziv v EU ali v svetu
- neposredno koristno za širšo javnost (projekti so javnega značaja!)
- oprijemljivi rezultati (produkt, nova metoda, raziskava, ki bo odgovorila na pereča vprašanja).

Prava izbira partnerjev:

- ravnotežje med znanstvenimi inštitucijami in podjetji
- izbira komplementarnih partnerjev

INTENSO
Predstavitev projekta

Svetovni zdravstveni problemi

Različne bolezni, za katere še ni zdravila

Leading Causes of Death in 2001

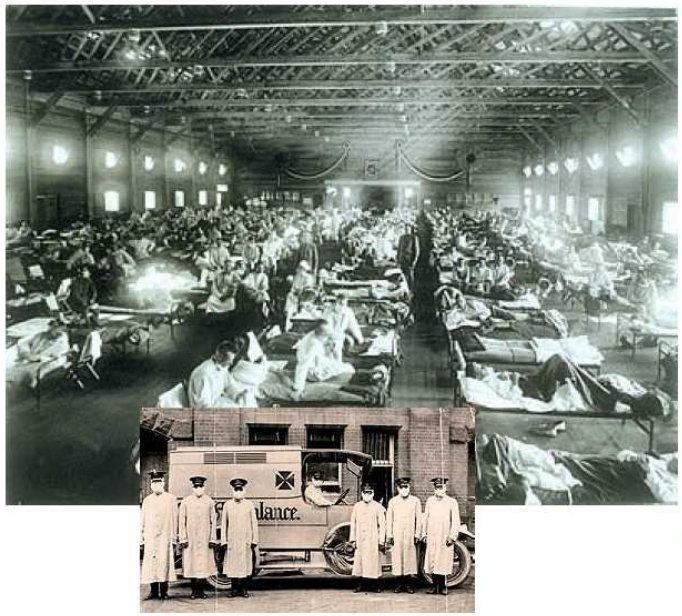
Developing Countries	Number of Deaths	Developed Countries	Number of Deaths
1. HIV/AIDS	2 678 000	1. Ischaemic heart disease	3 512 000
2. Lower respiratory infections	2 643 000	2. Cerebrovascular disease	3 346 000
3. Ischaemic heart disease	2 484 000	3. Chronic obstructive pulmonary disease	1 829 000
4. Diarrhoeal diseases	1 793 000	4. Lower respiratory infections	1 180 000
5. Cerebrovascular disease	1 381 000	5. Trachea/bronchus/lung cancers	938 000
6. Childhood diseases	1 217 000	6. Road traffic accidents	669 000
7. Malaria	1 103 000	7. Stomach cancer	657 000
8. Tuberculosis	1 021 000	8. Hypertensive heart disease	635 000
9. Chronic obstructive pulmonary disease	748 000	9. Tuberculosis	571 000
10. Measles	674 000	10. Self-inflicted	499 000

Source: WHO World Health Report 2002.

Svetovni zdravstveni problemi

Nevarnost pandemij, bioterorizem (npr. antraks)

„Spanish flu" of 1918



> 20 M dead
>100 million infection

Phyllis Burn (London)
Spitzbergs
Alaska

Far East Avian Influenza (HA)
Science 2004. March

Ptičja gripa

Svetovni zdravstveni problemi

Na antibiotike odporne bakterije

Bakterije, odporne na antibiotike, so postale vsakodnevna težava v bolnišnicah po vsej Evropi. Okužbe z bakterijami, odpornimi na antibiotike, je težko pozdraviti z ustreznim zdravljenjem z antibiotiki in lahko povzročijo zaplete pri bolnikih ter s tem podaljšano bivanje v bolnišnici, hujše bolezni in včasih celo smrt.

ZDRAV VESTN 2005; 74: 159–63 159

Strokovni prispevek/Professional article

PROTI METICILINU ODPORNA BAKTERIJA *STAPHYLOCOCCUS AUREUS* DOMAČEGA OKOLJA (CA-MRSA)

COMMUNITY-ACQUIRED METHICILLIN-RESISTANT *STAPHYLOCOCCUS AUREUS* (CA-MRSA)

Irena Grmek-Košnik[1], Urška Dermota[1], Borut Juteršek[2]

[1] Laboratorij za medicinsko mikrobiologijo, Zavod za zdravstveno varstvo Kranj, Gosposvetska 12, 4000 Kranj
[2] Oddelek za mikrobiologijo, Zavod za zdravstveno varstvo Celje, Gregorčičeva 5, 3000 Celje

Prispelo 2004-09-07, sprejeto 2005-02-03; ZDRAV VESTN 2005; 74: 159–63

Ključne besede: *proti meticilinu odporna bakterija Staphylococcus aureus (MRSA); MRSA domačega okolja (CA-MRSA); tipizacija; gelska elektroforeza v utripajočem polju*

Key words: *methicillin-resistant S. aureus; community-acquired methicillin-resistant S. aureus; typing; pulsed-field gel-electrophoresis*

Dnevnik.si

DOMOV | SLOVENIJA | LJUBLJANA | SVET | POSLOVNI | ŠPORT | MNENJA | MAGAZIN | KRONIKA

Domov | Zdravje Natisni: Velikost pisave:

12. januar 2012 (*nazadnje spremenjeno: 4:55 23. oktober 2012*) | **Zdravje**

Nemško piščančje meso leglo bakterij, odpornih proti antibiotikom

VURS nima podatkov, da bi pri nas živali v reji prejemale več zdravil in antibiotikov, kot bi bilo treba

Super odporna bakterija v bazenih in pitni vodi

New Delhi, 07.04.2011, 12:06 | STA / D.L. 46 Komentiraj Pošlji Tiskaj Velikost pisave

Bakterija NMD-1, ki je odporna na skoraj vse poznane antibiotike, kroži po vodovodnem sistemu indijskega velemesta New Delhi. Našli so jo v pitni vodi, v bazenih in v lužah ob cesti.

Kaj lahko naredimo?

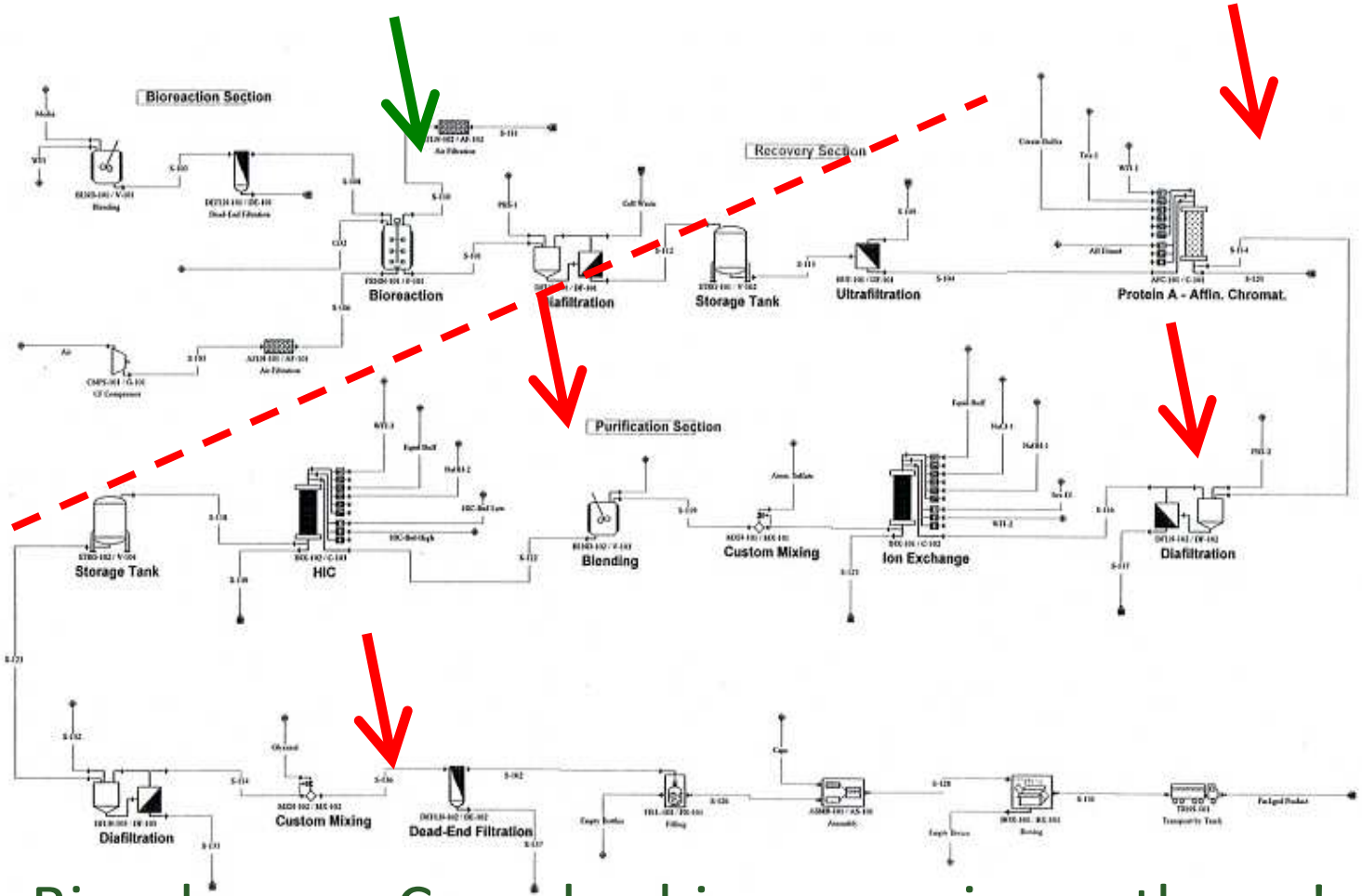
Razvoj novih zdravil in cepiv,

ki temeljijo na velikih bioloških makromolekulah oziroma sistemih!

Biofarmacevtiki

- Recombinant proteins
- **Antibodies – monoclonal**
- Vaccines
- Enzymes and toxins
- Blood products – human derived
- Others: Cultured cells, pDNA vaccines, anti-sense drugs, supra-macromolecular structures.

Proizvodnja biofarmacevtikov



Bio-pharma: Complex bioprocessing pathway!

Zaključni bioprocesi predstavljajo 80% problema!

Ozka grla zaključnih procesov

- Too many processing steps

- Limited throughput / productivity

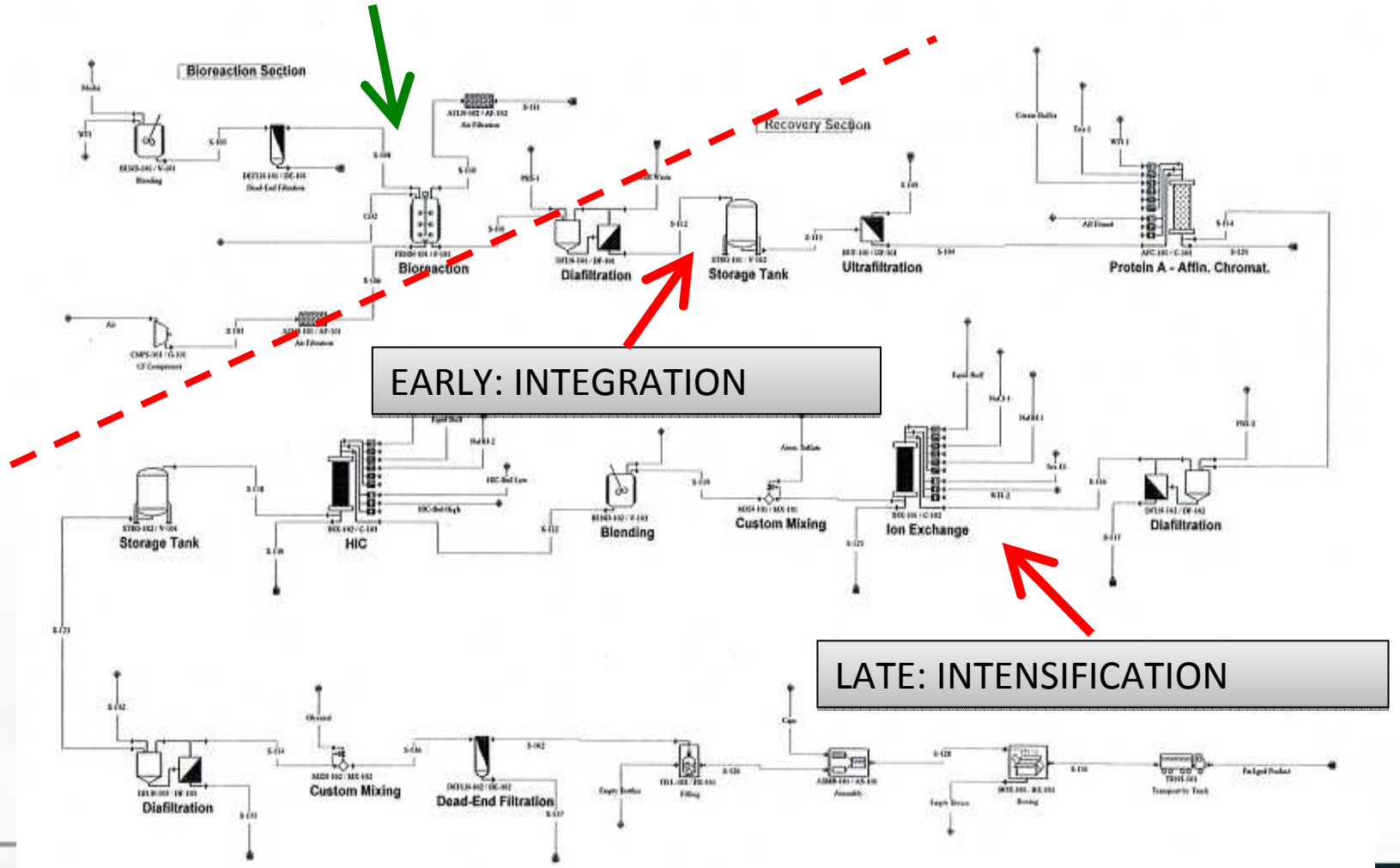
- Expensive materials / Cost of goods

- Resource intensive (water, energy)

- Inefficient handling of “new” products

Tradicionalni pristopi niso več zadostni!

Izboljšava z integracijo in intensifikacijo zaključnih procesov?



Naslov, namen projekta in cilji

Naslov: Gaining Productivity, Cost Efficiency and Sustainability in the Downstreaming Processing of Bio Products by novel Integration and Intensification strategies (INTENSO)

Namen:

•oceniti trenutno situacijo stanja zaključnih procesov bioproduktov in identificirati ozka grla

•predstaviti strategijo odpravljanja neučinkovitih metod/tehnik

Cilj:

•okrepitev/izboljšava posamezne tehnologije za določeno vrsto bioproduktov

•povezovanje posameznih operacij (tehnologij) v celoten (skupen) proces, tesno povezan z začetnimi procesi (fermentacijo), ki bi bil učinkovitejši od trenutno uporabljenih zaključnih procesov

Način in potek dela

Način in potek dela:

•multidisciplinarni pristop (proučili možnosti izboljšave procesne tehnologije kot tudi same bazične kemije, biologije in materialne znanosti v povezavi s procesom)

•4 vzporedni tehnološki sklopi (proučili obetavne in nove tehnologije ter jih poskušali optimirati za proizvodnjo različnih vrst bioproduktov)

Koncept projekta in vloge partnerjev

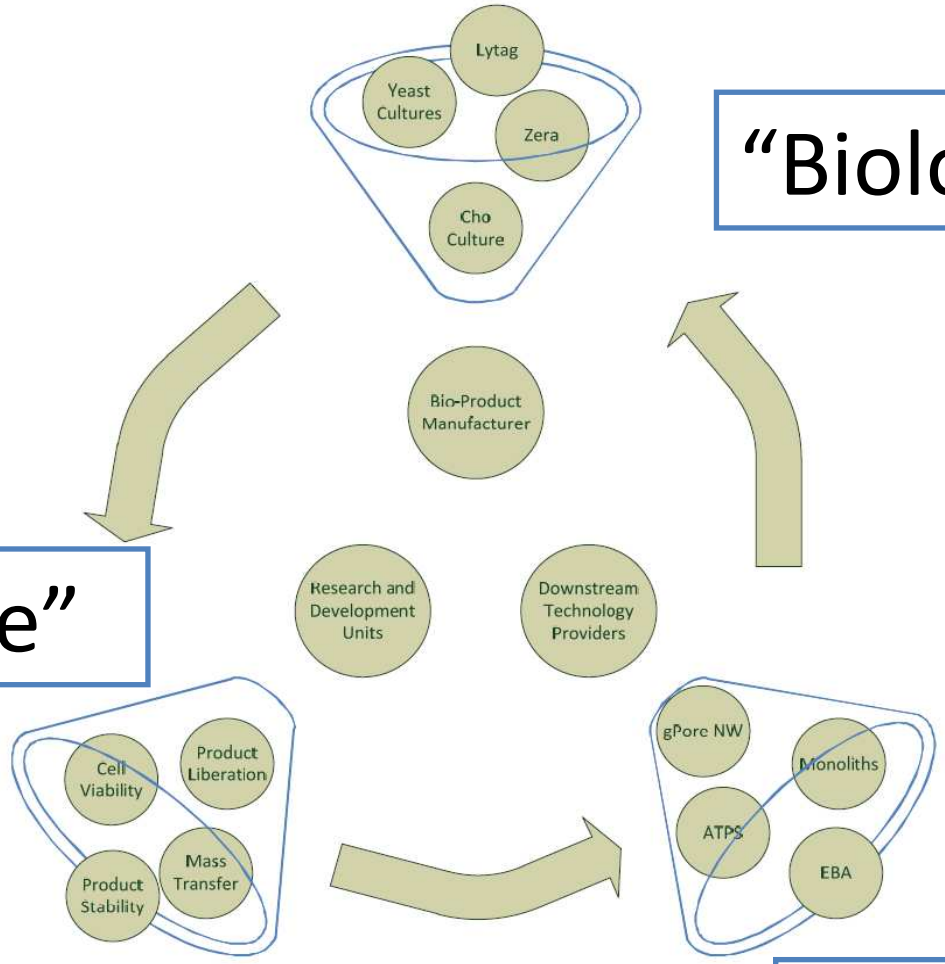


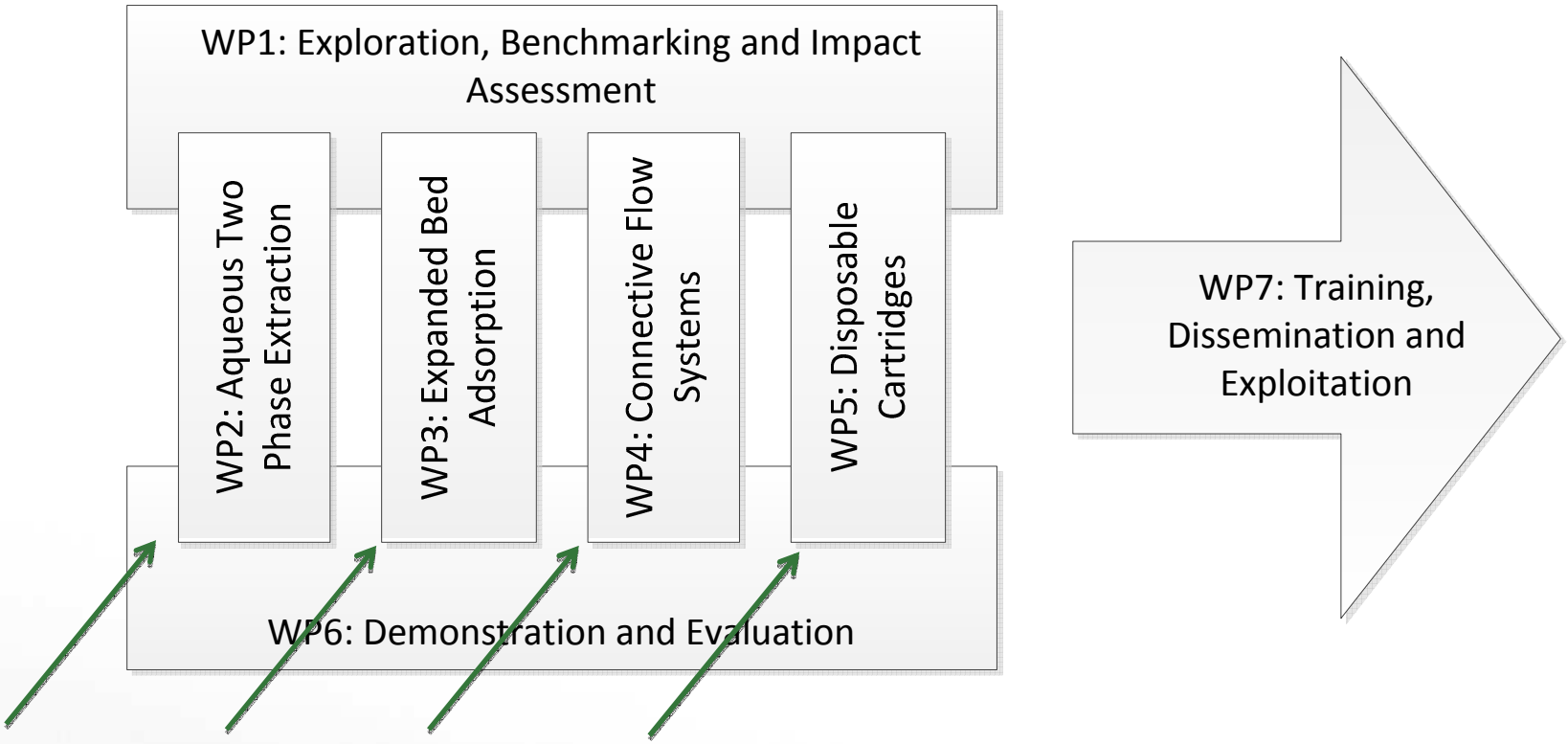
Figure 1: The Intenso Concept and Partner Roles

"Biology"

"Knowledge"

"Technology"

Sestava delovnih sklopov in njihova povezava



Biopharmaceuticals: mAbs, intracellular products from yeast expression hosts, pDNA/mRNA, VLP/vaccines.

Partnerji projekta

Organizacije članice projekta (16): 5 univerz, 1 podjetje za administracijo, ostalo so SME ali velika podjetja

No	Name	Short name	Country	Project entry month[10]	Project exit month
1	JACOBS UNIVERSITY BREMEN GGMBH	JacobsUni	Germany	1	54
2	BIA SEPARATIONS DOO	BIA	Slovenia	1	54
3	UNIVERSIDAD NACIONAL DE QUILMES	UNQ	Argentina	1	54
4	CHIPRO GMBH	Chipro	Germany	1	54
5	UNIVERSITAET FUER BODENKULTUR WIEN	BOKU	Austria	1	54
6	ICOSAGEN AS	IcoSagen	Estonia	1	54
7	SOFIISKI UNIVERSITET SVETI KLIMENT OHRIDSKI	UniSofia	Bulgaria	1	54
8	PROXCYS	PROXCYS	Netherlands	1	54
9	INSTITUTO SUPERIOR TECNICO	UniLisbon	Portugal	1	54
10	INFOCONSULT GESELLSCHAFT FUR INFORMATIONSTECHNIK MBH	InfoC	Germany	1	54
11	BIOMEDAL SL	Biomedal	Spain	1	54
12	VIRTUALPIE LTD	BHR	United Kingdom	1	54
13	ERA BIOTECH	EraBiotech	Spain	1	54
14	GENERI BIOTECH	GENERI	Czech Republic	1	54
15	ETHRIS GMBH	ethris	Germany	1	54
16	DSM BIOLOGICS COMPANY BV	DSM	Netherlands	1	54

Kako privabiti partnerje v projekt?

- Poznati interes posameznih partnerjev.
- Poiskati presek interesov, ki pa morajo biti KOMPLEMENTARNI!
- Če želite aktivno vključiti podjetja, mora biti vsebina projekta v interesu posameznega podjetja.

Primer delovnega sklopa 4

Cilji

- To manufacture sufficient amount of bioproducts of special characteristics (size, conformational stability), like pDNA, VLPs, and / or mRNA.
- To standardize and critically assess the current practice on the early recovery of such bio-products from cell cultures.
- To evaluate the performance of *convective flow systems* in capturing and purifying the mentioned entities.
- To attain process intensification via *radial technology* and to integrate all the elements above into robust and sustainable bioprocessing.

Partnerji v DS4

Partners:

- 2 BIA
- 8 PROXCYS
- 5 BOKU
- 14 GENERI
- 6 IcoSagen
- 15 ethris

Naloge DS4

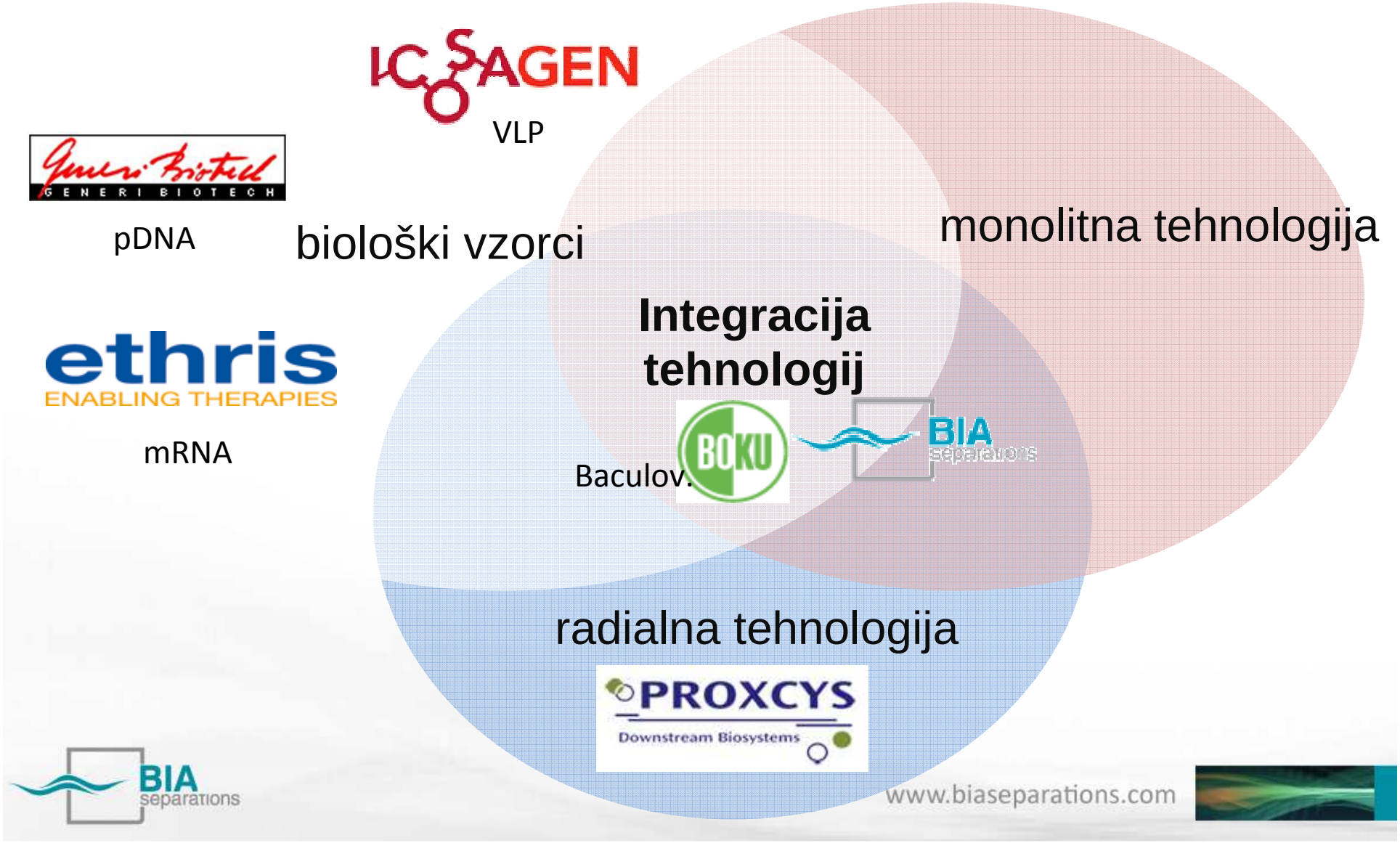
Task 4.1: Biological product manufacturing
(responsible Ethris)

Task 4.2: Monolith performance
(responsible BOKU)

Task 4.3: Radial technology
(responsible BIASep)

Task 4.4: Process integration
(responsible Proxcys)

Vloge posameznih partnerjev



BIA separations

www.biaseparations.com